MOMENTA PHARMACEUTICALS INC

FORM 10-K
(Annual Report)

Filed 02/26/16 for the Period Ending 12/31/15

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Telephone	617 491-9700
CIK	0001235010
Symbol	MNTA
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2015

Or

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

For the transition period from to

Commission file number: 000-50797

MOMENTA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

675 West Kendall Street, Cambridge, Massachusetts 02142
(Address of principal executive offices) (zip code)

Registrant's telephone number, including area code: **(617) 491-9700**

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on June 30, 2015, based on $22.81 per share, the last reported sale price of Common Stock on the Nasdaq Global Market on that date, was $1,535,271,963.

As of February 1, 2016, the registrant had 69,144,957 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 2016 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

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 Exchange Act. 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," "target," "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, product candidates and novel therapeutic programs; our partnered development and commercial programs and efforts to partner our un-partnered development programs; the timing of clinical trials and the availability of results; the significance and meaning of results of clinical trials, including without limitation, results from our necuparanib clinical trial; the timing of launch of products and product candidates; GLATOPA® (glatiramer acetate injection) product revenues and market potential; our M356-related patent litigation; Enoxaparin Sodium Injection revenues; collaboration revenues and research and development revenues; manufacturing, including our intent to rely on contract manufacturers; regulatory filings and approvals; and the sufficiency of our cash for future operations.

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

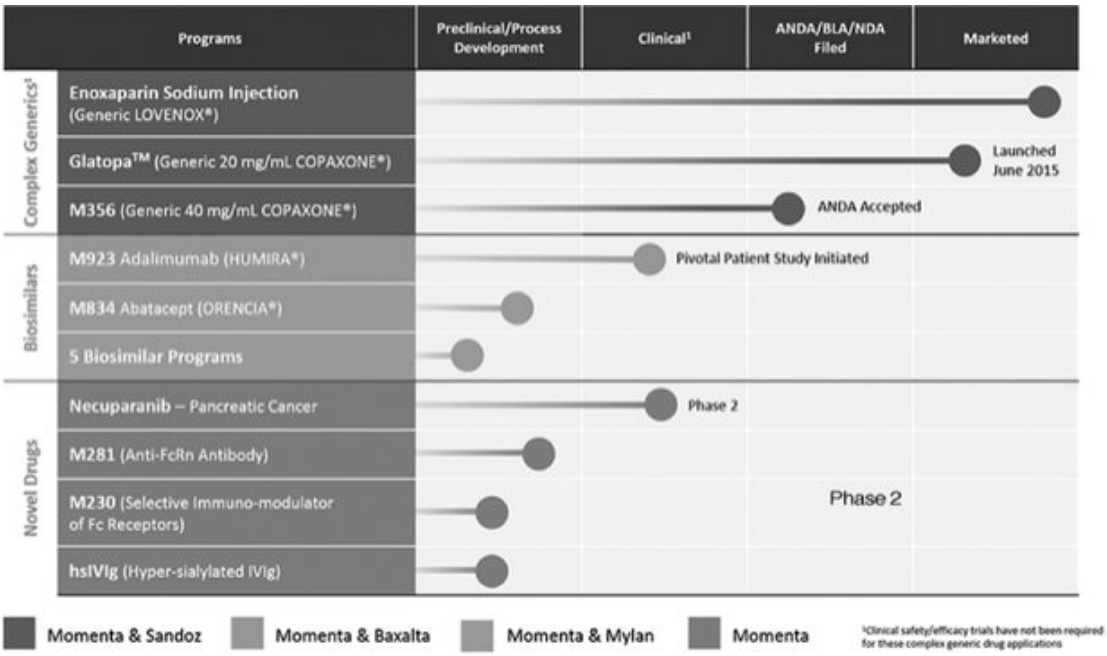
Our Company

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

We believe our complex systems analysis platform gives us a competitive advantage in developing complex generics, biosimilars and novel therapeutics, and today we are developing biosimilar and novel drug candidates using the structural and process insights gained from our work on complex generics. The analytic tools and methods, models and data sets, 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. The understanding of polysaccharides gained from our successful generic LOVENOX program has enabled the design and engineering of our novel oncology product candidate. 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 develop generic versions of complex drugs, which we refer to as complex generics. Generics are therapeutic equivalents of chemically synthesized brand name drugs that were approved by the FDA under New Drug Applications, or NDAs. Most chemically synthesized brand name drugs are simple small molecules that are relatively easy to duplicate. However, some brand name drugs, for example, LOVENOX and COPAXONE, are complex molecular mixtures that are difficult to analyze and difficult to reproduce as generics.

Our Programs

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

GLATOPA is a generic version of once-daily COPAXONE 20 mg/mL indicated for the treatment of patients with relapsing-remitting multiple sclerosis, or RRMS, 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 was approved by the FDA on April 16, 2015 and was launched on June 18, 2015. GLATOPA is the first "AP" rated, substitutable generic equivalent of once-daily COPAXONE. GLATOPA was developed and is being commercialized in collaboration with Sandoz, the generic pharmaceuticals division of Novartis. Under our collaboration agreement with Sandoz, Sandoz is responsible for commercialization of GLATOPA and we earn 50% of contractually-defined profits on Sandoz sales. The terms of our Sandoz collaboration for GLATOPA are further discussed below under " *Collaborations, Licenses and Asset Purchases—Sandoz* ."

For the year ended December 31, 2015, we recorded $43.4 million in product revenues from Sandoz' profits on sales of GLATOPA.

GLATOPA was formerly referred to as M356. M356 now refers to our generic product candidate for three-times-weekly COPAXONE 40 mg/mL.

M356—Generic Three-times-weekly COPAXONE® (glatiramer acetate injection) 40 mg/mL

M356 is our generic product candidate for three-times-weekly COPAXONE 40 mg/mL. M356 is being developed for commercialization in the United States in collaboration with Sandoz. Our application seeking approval of M356 was filed by Sandoz in February 2014 and is under review by the FDA. Our M356 formulation contains the same active pharmaceutical ingredient, or API, as GLATOPA, which we believe should help streamline the FDA review. To date, we are the only generic applicant for the three-times-weekly COPAXONE 40 mg/mL with an approved API.

Based on the scheduled September 2016 trial start date, and assuming customary patent litigation timelines, if we are successful in our challenge of the patents related to 40 mg/mL COPAXONE, we believe M356 could be approved following expiration of any 30-month stay, if applicable, and be on the market as early as the first quarter of 2017. In August 2015, the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, instituted an Inter Partes Review, or IPR, filed by a third party challenging the validity of several of the same patents relating to 40 mg/mL COPAXONE that are the subject of our patent litigation. We believe the outcome of this IPR could also impact our M356 litigation and launch timelines. The approval process and related patent challenge process are described below under " *Regulatory and Legal Matters—United States Government Regulation—"ANDA Approval Process" and "—Patent Challenge Process ANDAs* ."

Teva reported $3.2 billion and $3.1 billion in U.S. sales of COPAXONE (combined 20 mg/mL and 40 mg/mL) in 2015 and 2014, respectively.

Enoxaparin Sodium Injection—Generic LOVENOX®

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

We earned $5.1 million and $19.9 million in revenue on $113 million and $197 million in U.S. sales of Enoxaparin Sodium Injection by Sandoz in 2015 and 2014, respectively. 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

We seek to develop and commercialize biosimilars with a goal of leveraging our biocharacterization platform, analytic toolset and process control to achieve extrapolation across indications, interchangeability and reduced clinical trials. 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. The FDA may designate a biosimilar as interchangeable with its reference product, allowing the biosimilar to be substituted at the pharmacy for the reference product without the intervention of the prescriber. The FDA may also allow extrapolation across indications where information about the

reference product relating to its other indications are extrapolated to support approval of a biosimilar in one or more of those other indications. The biosimilar regulatory pathway is discussed in more detail below under *"Regulatory and Legal Matters—United States Government Regulation—Biosimilars."*

Our approach includes the following three-part strategy:

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

   We have put in place a high throughput biosimilar development engine to advance 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 strategy* .

   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 have identified and are collaborating with strategic partners who can bring best-in-class, global commercial capabilities and can help secure high quality, low cost manufacturing and distribution. Our lead program, M923, is being developed and commercialized in collaboration with Baxalta, and M834 and five other programs are being developed and commercialized in collaboration with Mylan. Both of these collaboration partners provide financial strength, manufacturing expertise and extensive commercial reach to better position our products for commercial success.

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 2013, the global biologics market represented approximately $150 billion in sales, with virtually the entire market composed of brand products. In 2020, global sales of biologics are expected to be approximately $240 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.

That potential, however, may be difficult to realize, in large part due to the challenges of successfully developing and manufacturing biosimilars. Biosimilars are biologics, or 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, while the market potential of biosimilars is great, the technical complexity involved and expertise and technical skill required to successfully develop and manufacture biosimilars poses significant barriers to entry. Our capabilities and our programs are designed to meet these challenges.

Our Programs

M923—Biosimilar HUMIRA® (adalimumab) Candidate

M923 is being developed 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 and is approved in 13 indications globally and 9 indications in the United States. HUMIRA is marketed globally by AbbVie.

M923 is being developed and commercialized in collaboration with Baxalta. We are responsible for development activities through submission of an Investigational New Drug application, or IND, to the FDA, or equivalent application in the European Union, and Baxalta is responsible for clinical development, manufacturing and commercialization activities. Upon approval and commercialization, we will receive royalties on sales of M923 at rates that increase based on the number of competitors, the interchangeability of M923 and the level of M923 sales. In addition, we are eligible to receive up to an additional $50 million in milestone payments from Baxalta relating to M923 to the extent that the pivotal clinical trial expenses are less than $50 million. The terms of our Baxalta collaboration are further discussed below under " *Collaborations, Licenses and Asset Purchases—Baxalta* ."

In February 2015, Baxalta commenced a randomized, double-blind, single-dose study 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, Baxalta initiated a pivotal clinical trial in patients with chronic plaque psoriasis for M923. The trial is a randomized, double blind, active control, multi-center, global study in patients with chronic plaque psoriasis to compare the safety, efficacy and immunogenicity of M923 with HUMIRA. Baxalta is planning to submit the first regulatory submission for marketing approval for M923 in 2017 and, subject to marketing approval and patent considerations, we expect first commercial launch to be as early as 2018.

AbbVie reported approximately $14.0 billion in worldwide sales of HUMIRA in 2015, including approximately $8.4 billion in the United States. Total worldwide sales of HUMIRA are expected to be approximately $18.8 billion in 2018, including approximately $12.3 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 use in treating patients with rheumatoid arthritis and juvenile idiopathic arthritis who have had an inadequate response to certain other currently available treatments. ORENCIA is currently in development for several high unmet need indications totaling greater than 1.5 million patients in the United States. ORENCIA is often a first choice option following patient failure on anti-TNFs. We could also see more use of ORENCIA as a first line biologic due to its demonstrated non-inferiority and equal time to efficacy versus HUMIRA in a double-blind, randomized trial in biological naïve rheumatoid arthritis patients. Analysts estimate that worldwide ORENCIA sales could increase to $2.7 billion by 2020. ORENCIA is marketed globally by Bristol-Myers Squibb and co-promoted by Ono Pharmaceutical in Japan.

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 and five other biosimilar product candidates. Under our collaboration agreement, we and Mylan will share equally costs and profits (losses) for such product candidates. We and Mylan will share development responsibilities across product candidates, and Mylan will lead commercialization of products. The terms of our Mylan collaboration are further discussed below under " *Collaborations, Licenses and Asset Purchases—Mylan* ."

We plan to initiate a clinical trial for M834 in mid-2016. ORENCIA's composition of matter patents expire in the United States in 2019. The U.S. PTAB instituted the IPR we filed challenging Bristol Myers Squibb's formulations patent '239 on ORENCIA. We expect a decision from the PTAB in January 2017. Provided there are no unexpected development, regulatory or patent challenge delays, we expect to be able to launch M834 in the 2020 timeframe. Previously, M834 was being developed and commercialized in collaboration with Baxalta. In February 2015, Baxalta terminated in part our collaboration as it relates specifically to M834 and worldwide development and commercialization rights to M834 reverted to us.

Bristol-Myers Squibb reported approximately $1.9 billion in worldwide sales of ORENCIA in 2015, including approximately $1.3 billion in the United States.

Other Biosimilar Programs in Collaboration with Mylan

We are also developing five other biosimilar candidates from our portfolio with Mylan, in addition to M834. We and Mylan will share equally costs and profits (losses) related to these earlier stage product candidates. We and Mylan will share development responsibilities across product candidates, and Mylan will lead commercialization of the products. 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 $13.0 billion in 2015, including approximately $7.7 billion in the United States, and are projected to be approximately $18.5 billion in 2018, including approximately $10.6 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 in the 2020-2025 timeframe to be among the first biosimilars on the market for each reference product.

Novel Therapeutics

Our Approach

We seek to identify novel agents and novel combinations of agents that may positively modulate new targets or multiple pathways in a disease. The majority of human diseases result from the interaction of a complex web of biologic systems. We believe that applying our complex systems analysis platform may enable new insights into the complex biology underlying diseases. This enhanced understanding should help us establish the relative role of different biological targets and related cell-to-cell signaling pathways in contributing to the disease process.

Our Programs

Necuparanib—Oncology Product Candidate

Necuparanib, formerly M402, is a novel oncology product candidate derived from heparin and engineered to have a broad range of potential effects on tumor cells and the environment in which tumor cells grow. The use of heparins to treat venous thrombosis in cancer patients has generated numerous reports of antitumor activity; however, the dose of these products has been limited by their anticoagulant activity. Necuparanib has been engineered to have significantly reduced anticoagulant activity while preserving the relevant antitumor properties of heparin, permitting delivery of substantially higher doses. We designed necuparanib based on our deep understanding of polysaccharides and our expertise in structural and biological characterization of heparins that we gained from successfully developing Enoxaparin Sodium Injection, which is produced from biologically derived heparin.

In June 2014, necuparanib received Orphan Drug Designation from the U.S. FDA for the treatment of pancreatic cancer. The FDA's Orphan Drug designation program provides orphan status to drugs and biologics intended to treat, diagnose or prevent rare diseases/disorders, defined as affecting fewer than 200,000 people in the United States. This designation provides certain incentives, including federal grants, tax credits, and waiver of Prescription Drug User Fee Act, or PDUFA, filing fees. A product with orphan drug status also has the potential to receive a seven-year orphan drug exclusivity once approved.

In December 2014, we received Fast-Track designation by the FDA for necuparanib as a first-line treatment in combination with ABRAXANE® (nab-paclitaxel) and gemcitabine in patients with metastatic pancreatic cancer. The FDA's Fast Track Drug Development Program is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. This designation allows for companies to interact with the FDA frequently to discuss issues such as study design, the extent of safety data required to support approval, the structure and content of an NDA, and other critical issues. In addition, such a product could be eligible for accelerated approval and/or priority review if supported by clinical data at the time of BLA, NDA, or efficacy supplement submission. If the FDA determines, after preliminary evaluation of clinical data submitted by a sponsor, that a Fast Track product may be effective, the FDA may also consider reviewing portions of a marketing application before the sponsor submits the complete application.

Nonclinical Development

Researchers have conducted a series of nonclinical experiments using mouse and rat tumor models including pancreatic, breast, colorectal, and ovarian cancers to test the hypothesis that necuparanib can modulate tumor progression and metastasis in these cancers. Necuparanib exhibits potent binding to multiple heparin-binding growth factors, adhesion molecules, and chemokines (such as VEGF, FGF-2, SDF-1 and P-selectin) and neutralizes these by blocking the interaction with their receptors or by dissolving their gradients in the tumor microenvironment. As a result, necuparanib has been shown in these models to inhibit tumor cell progression, metastasis, and angiogenesis. Additionally, the

nonclinical data showed that necuparanib in combination with gemcitabine prolonged survival and substantially lowered the incidence of metastasis, suggesting that necuparanib may have the potential to complement conventional chemotherapy in a range of cancers given its multi-targeted mechanism of action.

Clinical Development

In 2012, we initiated a Phase 1/2 clinical trial of necuparanib in patients with advanced metastatic pancreatic cancer. The trial consists of two parts: Part A, or Phase 1, an open-label, multiple ascending dose escalation study evaluating necuparanib in combination with ABRAXANE and gemcitabine; and Part B, or Phase 2, a randomized, controlled, proof of concept study to evaluate the antitumor activity of necuparanib in combination with ABRAXANE and gemcitabine, compared with ABRAXANE and gemcitabine alone.

In October 2014, we successfully completed and reported top-line data from Phase 1. Phase 1 involved escalating daily necuparanib doses in combination with 125 mg/m ^{2} ABRAXANE and 1000 mg/m ^{2} gemcitabine (Days 1, 8, and 15 of each 28-day cycle) in patients with metastatic pancreatic cancer. The necuparanib starting dose was 0.5 mg/kg, which was increased via a modified 3+3 design until a maximum tolerated dose of 5 mg/kg was determined. ABRAXANE was added to the treatment regimen starting with Cohort 3 following release of the Phase 3 ABRAXANE + gemcitabine data in 2013. Thirty-nine patients (12 patients in the first two cohorts and 27 patients in the five subsequent cohorts) received necuparanib as of data cutoff and were included in the analyses. In June 2015 at the American Society of Clinical Oncology annual meeting, we reported more mature data from Phase 1 which continued to show acceptable safety and tolerability and encouraging signals of activity, including the following:

- Adding necuparanib to ABRAXANE and gemcitabine did not appear to increase the toxicity profile associated with ABRAXANE and gemcitabine alone.

- Of the 24 patients who received at least one dose of necuparanib in combination with ABRAXANE plus gemcitabine, the median overall survival was 14.2 months. Also, within a subset of 16 patients who completed one cycle and had at least one scan on treatment, the median overall survival was 15.3 months.

- Of the 15 patients treated with necuparanib in combination with ABRAXANE plus gemcitabine that completed Cycle 1 and had at least one follow-up measurement for CA19.9 (a biomarker predictive of long-term outcome and treatment response in pancreatic cancer), 93% had a greater than 50% decrease from baseline, and 100% had a greater than 20% decrease from baseline.

We believe the safety data and early signals of activity are encouraging and that the 5 mg/kg dose has the potential to provide significantly higher levels of activity against multiple cancer targets than traditional anticoagulant heparins have achieved. We believe these results, combined with nonclinical data in other cancer models, and necuparanib's differentiated, multi-targeted mechanism of action, suggest the possibility of combining necuparanib with other chemotherapy and targeted therapy standards of care in a variety of other tumor types. We continue to collect data from Phase 1 of the trial and plan to publish and/or present updated results later this year.

In October 2014, we initiated Phase 2 of the Phase 1/2 trial. In November 2015, we paused study enrollment in Phase 2 of the trial following our acceptance of recommendations from our Data Safety Monitoring Board, or DSMB, to develop guidelines for diagnosing and managing thrombocytopenia, based on a limited number of specific toxicities observed in the study. The DSMB noted that there were no safety signals that warranted discontinuation of dosing in patients already being treated, unblinding the results, or closing the study. In December 2015, we amended the study protocol to further reinforce these guidelines and resumed patient enrollment. We continue to enroll patients in

Phase 2 of the trial. We expect data from this randomized trial to be available in the second half of 2017. Subject to successfully completing clinical trials and obtaining marketing approval, we believe necuparanib could be on the market in the 2020-2021 timeframe, or potentially earlier under Fast-Track Designation.

Other Novel Therapeutics Programs

We are applying our advanced understanding of the complex biology underlying the anti-inflammatory effects of intravenous immunoglobulin, or IVIg, and the biologic impact of sialylation, a method of adding sialic acid to proteins, on IVIg's activity, to the development of the following three novel therapeutic programs:

- *M281, our Anti-FcRn program*— The Anti-FcRn antibody is a fully-human monoclonal antibody that blocks the neonatal Fc receptor, or FcRn. This receptor recycles IgG antibodies, enabling a long half-life. The blocking of this receptor with our antibody effectively inhibits the binding of IgGs and leads to their rapid clearance. We believe these data indicate high potential for acute and chronic / intermittent therapies in a broad range of autoantibody driven disease. We have completed IND-enabling toxicology studies. M281 exhibits high affinity to human and non-human FcRn in preclinical studies and shows selective induction of human and non-human IgG clearance. We plan to advance this program with a goal of entering clinical development in mid-2016.

- *M230, our SIF3 program*— The selective immunomodulator of Fc receptors, or SIF3, is a novel recombinant protein containing three IgG Fc regions joined carefully to maximize activity. Nonclinical data has shown that this construct enhances the molecules' avidity and affinity for the Fc receptors. Using these data, we are seeking to develop an IVIg-like efficacy profile at lower doses, potentially reducing the risks associated with plasma-derived products. We plan to advance this program with a goal of entering clinical development in 2017.

- *hsIVIg program*— Hyper-sialylated IVIg, or hsIVIg, is a hyper-sialylated version of IVIg. IVIg, which contains pooled, human immunoglobulin G, or IgG, antibodies purified from blood plasma, is indicated to treat several inflammatory diseases, including idiopathic thrombocytopenic purpura, or ITP, Kawasaki disease, and chronic inflammatory demyelinating polyneuropathy, or CIDP. 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. Moreover, the IVIg that is available is predominantly used to treat primary immunodeficiency for diseases such as AIDS. Increasing demand for IVIg products already exceeds available supply worldwide thus limiting broader clinical applications. Many in-vivo models have shown hsIVIg to have increased anti-inflammatory activity at a much lower dose than IVIg, which may enable a simpler and faster administration with the potential for superior efficacy and reduced batch-to-batch variation compared to IVIg. We are currently identifying and pursuing potential collaboration opportunities to further develop and commercialize this program.

We believe these early stage programs 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.

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 AG, or Sandoz; and a stock purchase agreement and an investor rights agreement, with Novartis Pharma AG, or Novartis. Under the 2006 Sandoz Collaboration Agreement, we and Sandoz agreed to exclusively collaborate on the development and commercialization of GLATOPA and M356, 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 and M356, we are generally responsible for all of the development costs in the United States. For GLATOPA and M356 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 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. We are entitled to earn 50% of contractually-defined profits on Sandoz' worldwide net sales of M356, if and when M356 is commercialized. Profits on net sales of GLATOPA and M356 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. Sandoz is responsible for funding all of the legal expenses incurred under the 2006 Sandoz Collaboration Agreement; however a portion of certain legal expenses, including any patent infringement damages, can be offset against the profit-sharing amounts in proportion to our 50% profit sharing interest. In the year ended December 31, 2015, we earned a $10.0 million regulatory milestone payment upon GLATOPA receiving sole FDA approval and an additional $10.0 million milestone payment upon the first commercial sale. We are eligible to receive up to $120.0 million in additional milestone payments upon the achievement of certain commercial and sales-based milestones for GLATOPA and M356 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 M356, if clinical trials are required for regulatory approval of M356.

Under the stock purchase agreement, we sold approximately 4.7 million shares of our common stock to Novartis for an aggregate purchase price of $75.0 million, representing a premium of $13.6 million based on the closing price of our common stock on the NASDAQ Global Market on the date of purchase. As of December 31, 2015, Novartis owned approximately 6.8% of our outstanding common stock. Pursuant to the investor rights agreement, we granted to Novartis "piggyback" and demand registration rights under the Securities Act of 1933, as amended, with respect to the shares of common stock purchased under the stock purchase agreement.

Mylan

We and Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., or Mylan, 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 world-wide basis, to develop, manufacture and commercialize six of our biosimilar candidates, including M834.

Under the terms of the Mylan Collaboration Agreement, Mylan has agreed to pay us a non-refundable upfront payment of $45 million. In addition, we and Mylan will 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.

Baxalta

We and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively referred to as "Baxter") entered into a global collaboration and license agreement effective February 2012, or the Baxter Collaboration Agreement, to develop and commercialize biosimilars, including M923. In connection with Baxter's internal corporate restructuring in July 2015, Baxter assigned all of its rights and obligations under the Baxter Collaboration Agreement to Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated (collectively, "Baxalta"). In light of the assignment, all references to "Baxter" and the "Baxter Collaboration Agreement" have been replaced with references to "Baxalta" and the "Baxalta Collaboration Agreement," respectively.

Under the Baxalta Collaboration Agreement, we and Baxalta agreed to collaborate, on a world-wide 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: M511, a biosimilar candidate of AVASTIN® (bevacizumab). In December 2013, Baxalta terminated its option to license M511 under the Baxalta Collaboration Agreement following an internal portfolio review. In February 2015, Baxalta's right to select additional programs expired without being exercised. Also, in February 2015, Baxalta terminated in part the Baxalta Collaboration Agreement as it relates specifically to M834 and all worldwide development and commercialization rights for M834 reverted to us. The Baxalta Collaboration Agreement remains in effect and unchanged with respect to M923.

Under the Baxalta Collaboration Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize M923 for all therapeutic indications. We have 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 include high-resolution analytics, characterization, and product and process development. Baxalta is responsible for clinical development, manufacturing and commercialization activities and will exclusively distribute and market M923. We have 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, will be borne by the parties in varying proportions, depending on the type of

expense and the stage of development. We will generally be 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 will be borne by Baxalta.

Baxalta has a right of first negotiation with respect to collaborating with us on the development of any biosimilar product candidate that could compete with M923 based on the same mechanism of action. This right is effective until December 2017, subject to certain restrictions as outlined in the Baxalta Collaboration Agreement.

Under the terms of the Baxalta Collaboration Agreement, we received an initial cash payment of $33.0 million, a $7.0 million license payment for achieving pre-defined "minimum development criteria" for M834, and $12.0 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 remain eligible to receive from Baxalta, in aggregate, up to $50 million in regulatory milestone payments for M923, on a sliding scale, where, based on the product's regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval.

In addition, if M923 is successfully developed and launched, Baxalta will be 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 be slightly more than double the base royalty.

The term of the collaboration will continue throughout the development and commercialization of M923 on a country-by-country basis until there is no remaining payment obligation with respect to the product in the relevant territory, unless earlier terminated by either party pursuant to the terms of the Baxalta Collaboration Agreement.

The Baxalta Collaboration Agreement may be terminated by:

- either party for breach by or bankruptcy of the other party;
- Baxalta for its convenience; or
- us in the event Baxalta does not exercise commercially reasonable efforts to commercialize M923 in the United States or other specified countries, provided that we also have certain rights to directly commercialize M923, as opposed to terminating the Baxalta Collaboration Agreement, in event of such a breach by Baxalta.

In January 2016, Baxalta and Shire plc announced an agreement under which Shire will combine with Baxalta, subject to shareholder and regulatory approvals.

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, 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 fifteen years of the date of the purchase agreement. Between 2009 and 2011, we made cash payments to Parivid of $7.3 million and issued 91,576 shares of our common stock valued at $10.92 per share to Parivid in satisfaction of certain milestones under the purchase agreement. Under the purchase agreement, which was amended in August 2009 and July 2011, Parivid remains eligible to receive up to $4.0 million of our common stock

if GLATOPA remains the sole generic COPAXONE 20 mg product on the market through the one-year anniversary of 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 over 100 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 oncology and autoimmune disease;
- composition of matter, methods of use, and methods of making certain novel low molecular weight heparins, including necuparanib;
- composition of matter and use of certain heparinases, heparinase variants and other enzymes; and
- methods and technologies for the analysis and synthesis of polysaccharides.

A portion of our patent portfolio covering methods and technologies for analyzing and characterizing polysaccharides consists of patents and patent applications owned and licensed to us by the Massachusetts Institute of Technology, or M.I.T. In addition, a portion of the claims in our patent portfolio covering the composition of matter of naturally occurring heparinases, heparinase variants and other enzymes, the use of these heparinases and enzymes in the characterization of sugars consists of patents and patent applications that are owned and licensed to us by M.I.T.

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 novel heparin or other 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 manufacturing any products. 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 and M356. Under the Baxalta Collaboration Agreement, Baxalta is responsible for clinical and commercial manufacturing of M923. 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.

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, 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 and M356. Under the Baxalta Collaboration Agreement, Baxalta is responsible for commercializing M923. 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.

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 approval to market 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. 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

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 such products as heparins and 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.

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 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. The review of the Citizen Petition and the preparation of the

FDA response, however, involved significant legal and regulatory resources that may have extended the time for FDA review and approval of the 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-months 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.

Biosimilars

With the enactment of federal healthcare reform legislation in March 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. For example, heparin-based products may now have the potential option of filing for approval as either a drug or a biologic.

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 addition, the FDA has not established final guidance for demonstrating interchangeability and applicants will need to develop appropriate scientific evidence to support their filings. 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. In February 2012, the FDA published draft guidance documents for the development and registration of biosimilars and interchangeable biologics. The draft 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. 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 or branded 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;

- 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;
- completion of developmental chemistry, manufacturing and controls activities and manufacture under current Good Manufacturing Practices, or cGMP;
- submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- 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; 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. For example, heparin based products may now have the option of filing for approval as a biologic. 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 or BLA, the FDA will inspect the facility or the facilities at which the product is manufactured. The FDA will not approve the product unless 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 or BLA, 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 will be 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 will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products if and when we enter 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®—Generic COPAXONE® (glatiramer acetate injection) 20 mg/mL

GLATOPA 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 M356 is approved, M356 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 more than 70% of the overall U.S. glatiramer acetate market (20 mg/mL and 40mg/mL). 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. Currently, GLATOPA 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 could compete with 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, and Amneal Pharmaceuticals. Other ANDAs or other regulatory applications may have been submitted or may be submitted in the future. In addition, GLATOPA competes (and M356, if approved will compete) with alternative multiple sclerosis therapies that compete with COPAXONE in the United States. These currently include, among others, Rebif (interferon-beta-1a), marketed by EMD Serono Inc. and Pfizer Inc.; Avonex (interferon beta-1a), Tysabri (natalizumab), Tecfidera (dimethyl fumarate), and Plegridy (peginterferon beta-1a), each marketed by Biogen Idec Inc.; Betaseron (interferon-beta-1b), marketed by Bayer Schering Pharma; Extavia (interferon-Beta-1b) and Gilenya

(fingolimod), each marketed by Novartis Pharmaceuticals Corporation; Lemtrada (alemtuzumab), marketed by Sanofi and Bayer; and Aubagio (teriflunomide), marketed by Sanofi.

Biosimilars

If approved, our biosimilar candidates would compete with their applicable reference products, as well as other biosimilars of those reference products. Currently, Amgen, Sandoz, Samsung Bioepis, Reliance Life Sciences, Fujifilm Kyowo Kirin Bio., Pfizer, Boehringer Ingelheim, Oncobiologics, Coherus, LG Life Sciences, Celltrion, Biocon/Mylan, Epirus Biopharmaceuticals and Genor have biosimilars of HUMIRA in clinical development. Worldwide, there are two biosimilar adalimumab products approved, one from Torrent Pharmaceuticals and one from Zydus Cadila, both marketed in India. Alphamab, bioXpress, Dr. Reddy's Laboratories, Harvest Moon, and Oncobiologics have announced they are developing a biosimilar of ORENCIA. Other companies, including Biogen Idec Inc. and Teva, have also begun, or have announced their intention, to develop and commercialize biosimilars. Many of these companies are significantly larger than us, have substantially greater financial resources and have significant pre-existing resources to devote to their biosimilars business. In addition, our biosimilar candidates, if approved, would compete with alternative therapies that compete with their applicable reference products.

Novel Therapeutics

Our novel product pipeline will also face substantial competition from major pharmaceutical and other biotechnology companies. Necuparanib will face competition from existing pancreatic cancer treatments, like the FOLFIRINOX regimen, which is a combination of five chemotherapy agents, as well as from novel mechanisms of action in development. Among the novel mechanisms of action in development are several other heparin-based mechanisms. Progen Pharmaceuticals, Cantex Pharmaceuticals and Sigma Tau Research are believed to be developing compounds with a heparin-based mechanism of action for oncology indications. Other novel products in the pipeline for metastatic pancreatic cancer that may compete with necuparanib in the first line treatment setting include the assets PEGPH20 from Halozyme Therapeutics and demcizumab from OncoMed Pharmaceuticals, among others, all of which are also currently being evaluated in combination with gemcitabine and nab-paclitaxel in this patient population. Necuparanib may also face competition from immunotherapy compounds in combination with novel agents.

Our development work focused on Fc biology, which has yielded two named product candidates: M230, an Fc multimer, and M281, an anti-FcRn product. 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, Dyax, Syntimmune and argenx, are developing an FcRn targeted agent. UCB's compound completed a phase I clinical trial in October 2015, argenx's compound is currently in phase I, and the compounds from HanAll, Dyax, and Syntimmune are in nonclinical development.

Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2015, we had 258 employees, including 79 employees who hold Ph.D. degrees and 3 employees who hold M.D degrees. 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 2015 was $126.0 million, compared with $106.5 million in 2014 and $104.0 million in 2013.

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, 2015 have come from our collaborators and are based solely on activities in the United States. Our long-lived assets were $25.4 million, $30.0 million and $30.3 million at December 31, 2015, 2014, and 2013, 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, N.E., Room 1580, 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 material regarding issuers that file electronically with the Securities and Exchange Commission.

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

We make available free of charge on our website 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 stock involves a high degree of risk. You should carefully consider the risks and 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 stock. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

Risks Relating to Our Business

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, 2015, our accumulated deficit was $452.4 million. We may incur annual operating losses over the next several years as we expand our drug development, commercialization and discovery efforts. In addition, we must successfully develop and obtain regulatory approval for our drug candidates, and effectively manufacture, market and sell any drugs 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 drugs 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.

Even if M356 (our generic product candidate for three-times-weekly COPAXONE 40 mg/mL) is approved by the FDA, if Teva is successful in the current M356 ANDA-related patent infringement litigation, we and Sandoz may not be able to launch M356 until the relevant COPAXONE patents expire, or we may have to pay significant damages if we launch before those patents expire. In addition, Teva may allege that we and Sandoz, in manufacturing and selling GLATOPA and/or M356, are infringing COPAXONE patents other than those at issue in our current M356 patent litigation. If this occurs we may expend substantial resources in resulting litigation, the outcome of which would be uncertain. Any unfavorable outcome in such litigation could decrease or halt GLATOPA sales prior to a successful defense of such litigation or expiration of any such patents, and we and Sandoz may incur significant damages, reducing our profits and having a material adverse effect on our business.

Should Teva succeed in the current M356 ANDA-related patent infringement litigation, the launch of M356, if approved, may not occur until the patents expire, which would impair our ability to commercialize M356 and would harm our business and financial condition. If M356 is approved by the FDA prior to a decision in the patent infringement litigation, and we and Sandoz launch prior to such decision, we may not be able to utilize M356 product revenue until the conclusion of the litigation, and if Teva is ultimately successful, we and Sandoz may be liable for significant damages, including damages in excess of M356 product revenue, and our business and financial condition would be materially harmed. The possibility of incurring liability for such damages may reduce the scope of, or may delay, any launch of M356 prior to a favorable outcome of the patent infringement litigation. In addition, if we are unsuccessful in litigation, or pending the outcome of litigation or while litigation is pending, a court could issue a temporary injunction or a permanent injunction preventing us from manufacturing

and selling M356 and prohibiting the use of previously manufactured product for commercial sale until a favorable outcome of the litigation or the expiration of the patents.

Teva may also assert that our manufacturing and sale of M356 and/or GLATOPA infringes COPAXONE-related patents other than those at issue in the current M356 ANDA-related patent infringement litigation, including patents that may issue in the future. If so, we would expect to incur significant expenses under the terms of our collaboration with Sandoz to respond to and litigate these claims. Furthermore, we may be ordered to pay damages from the sale of M356 and/or GLATOPA if we are found to have infringed Teva's patents. Litigation concerning intellectual property and proprietary technologies can be protracted and expensive, and can distract management and other key 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, M356, M923 and M834, are approved and successfully commercialized, our business would suffer.

Generic versions of our products can contribute most significantly to revenues at the time of their launch, especially with limited competition. As such, the timing of competition can have a significant impact on our financial results. We expect that certain of our product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. For example, Mylan announced that the FDA had accepted for filing its ANDAs for generic versions of COPAXONE and Synthon announced that it 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.

Furthermore, as patents for branded products and related exclusivity periods expire, manufacturers of generic products may receive regulatory approval for generic equivalents and may be able to achieve significant market share. As this happens, and as branded manufacturers launch authorized generic versions of such products, market share, revenues and gross profit typically decline, in some cases, dramatically. If any of our current or potential future generic or biosimilar product offerings, including GLATOPA, M356, M923 and M834 enter markets with a number of competitors, we may not achieve significant market share, revenues or gross profit. In addition, as other generic products are introduced to the markets in which we participate, the market share, revenues and gross profit of our generic products would likely decline significantly. In addition, the first biosimilar determined to be interchangeable with a particular reference product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that reference product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). A determination that another company's product is interchangeable with HUMIRA or another of the reference brand products for which we have a product candidate prior to approval of M923 or other applicable product candidate may therefore delay the potential 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 name brand drug or reference product, such as COPAXONE or HUMIRA, 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 name brand drug or 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 brand 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 brand product market and significantly reduce the market for the original reference brand 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 more than 70% of the overall U.S. glatiramer acetate market (20 mg/mL and 40mg/mL). As a result, the market potential for GLATOPA 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 name brand drug or 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. Brand name 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 brand product to our generic product and generic or biosimilar product candidates, such as COPAXONE, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product 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 brand 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.

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 agreements, we may breach those agreements and our collaboration partners could terminate those agreements.

As of December 31, 2015, we had cash, cash equivalents and marketable securities totaling approximately $350 million. For the year ended December 31, 2015, we had a net loss of $83.3 million and cash used in operating activities of $71.5 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 drug 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;
- the successful commercialization of our 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 milestone payments under our Baxalta Collaboration Agreement and continuation payments under our Mylan Collaboration Agreement;
- the continuation of activities under our Baxalta Collaboration Agreement without disruption following the combination of Baxalta and Shire plc;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation, including with Amphastar relating to enoxaparin, that is not otherwise covered by our collaboration agreement, 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 collaborations for our non-partnered programs, 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 agreements and equity financings, including utilization of our At-the-Market financing facility. 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. Any additional capital raised through the sale of equity may dilute existing investors' percentage ownership of our common stock. Capital raised through debt financing would require us to make periodic interest payments and may impose potentially restrictive covenants on the conduct of our business. Additional funds may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. 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 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.

We may need to enter into collaborations, joint ventures or other 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, our business could be adversely affected.

Because we have limited or no internal capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we may need to enter into strategic alliances with other companies. For example, we have entered into collaboration agreements to develop and commercialize our complex generics programs and our biosimilar programs. In the future, we may also find it necessary to form similar strategic alliances with major pharmaceutical companies to jointly develop and/or commercialize other product candidates across our product areas. 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. Even if we do succeed in securing such alliances, we may not be able to maintain them if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. If we are unable to secure or maintain such alliances 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.

Our future GLATOPA product revenue is dependent on the continued successful commercialization of GLATOPA.

Our near-term ability to generate GLATOPA product revenue depends, in large part, on Sandoz' continued ability to manufacture and commercialize GLATOPA, maintain pricing levels and market share and compete with Teva's three-times-weekly COPAXONE 40 mg/mL, which currently accounts for more than 70% of the overall U.S. glatiramer acetate market (20 mg/mL and 40mg/mL). Because GLATOPA is only a substitutable generic version of the once-daily 20 mg/mL formulation of COPAXONE, the market potential of GLATOPA is negatively impacted by the conversion of patients from once-daily COPAXONE to three-times-weekly COPAXONE. In addition, other competitors may in the future receive approval to market generic versions of the 20 mg/mL formulation 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 product revenue is dependent on the continued successful manufacture and commercialization of Enoxaparin Sodium Injection .

Our near-term ability to generate Enoxaparin product revenue depends, in large part, on Sandoz' continued ability to manufacture and commercialize Enoxaparin Sodium Injection, maintain pricing

levels and market share 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. In the year ended December 31, 2015, we received $5.1 million in product revenue from Sandoz' sales of Enoxaparin Sodium Injection, and we do not anticipate significant enoxaparin revenue in the near term. As a result, our business, including our near-term financial results, may suffer.

If our patent litigation against Amphastar related to Enoxaparin Sodium Injection is not successful or Amphastar or others are successful in anti-trust lawsuits against us relating to Enoxparin 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 having been in effect, we could be liable for up to $35 million of the security bond for such damages. This amount may be increased if Amphastar is successful in their motion to increase the amount of the security bond. Moreover, if Amphastar or others are successful in the anti-trust lawsuits 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 brand name drugs and 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 could be expected to use similar tactics to delay competition from 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;
- 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 brand 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, 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 40mg M356 ANDA, and seek to delay or prevent the FDA approval of the 40mg M356 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 products, which could have a material adverse effect on our sales and profitability.

If we or our collaborative partners and other third parties are unable to satisfy FDA quality standards and related regulatory requirements, experience manufacturing difficulties or are unable to manufacture sufficient quantities of our products or product candidates, 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 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. We, our collaborative partners or our third-party contractors may have difficulty meeting FDA manufacturing requirements, including, but not limited to, reproducibility, validation and scale-up, and continued compliance with current good manufacturing practices requirements. If we, our collaborative partners or our third-party manufacturers or suppliers are unable to satisfy the FDA manufacturing requirements for our products and product candidates, or are unable to produce our products in sufficient quantities to meet the requirements for the launch of the product or to meet

market demand, our revenue and gross margins could be adversely affected, which could have a material adverse impact on our business.

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, 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.

If we successfully develop and obtain approval for our drug candidates, we will face competition based on many different factors, including:

- the safety and effectiveness of our products;
- with regard to our generic or 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 decline.

Generic pharmaceutical biosimilars products 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 such as Express Scripts or CVS.

These purchasers and pharmacy benefit management firms rely on competitive bidding, discounts and rebates across their purchasing arrangements. We also 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 these relationships. The GPOs, pharmacy benefit management firms 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 GPOs, pharmacy benefit management firms, and customers, including wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our products. If we or our collaborators are unable to establish and maintain 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 superior or biosimilar therapeutic effect 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, biosimilarity or interchangeability testing of our complex generic or 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. Many stock options granted to our executives and employees are now under pressure given our recent stock performance. 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 internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure or security 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, and the trading price of our common stock could be adversely affected.

As we evolve from a company primarily involved in drug discovery and development 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 will 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 drug 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 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. 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 Development and Regulatory Approval

The future success of our business is significantly dependent on the success of our M356 product candidate. If we are not able to obtain regulatory approval for the commercial sale of our M356 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 M356. Our application for M356 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 M356:

- 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 M356 to COPAXONE 40 mg/mL will be based, in part, on our demonstration of the chemical equivalence of our versions to their respective reference listed drugs. The FDA may not agree that we have adequately characterized M356 or that M356 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 M356 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 M356 could be delayed or prevented or become more expensive. Delays in any part of the process or our inability to obtain regulatory approval for M356 could adversely affect our operating results by restricting or significantly delaying our introduction of M356.

Although health care reform legislation that establishes a regulatory pathway for the approval by the FDA of biosimilars has been enacted, the standards for determining biosimilarity and interchangeability for biosimilars are only just being implemented by the FDA. 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 follow-on versions of biologic and complex protein products remains uncertain, even following the recent 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 guidance on certain matters concerning approval of biosimilars, including quality considerations and scientific considerations and to date, only one biosimilar product has been approved, and, to our knowledge, only a limited number of biosimilar applications have been accepted for review by the FDA, and one application has been approved for a biosimilar under the 351(k) pathway. The pathway contemplates approval of two categories of follow-on biologic products: (1) biosimilar products, which are highly similar to the existing brand product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences from the brand 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 brand 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 brand 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 brand company's and patent owner's counsel;
- the inclusion of multiple potential patent rights in the patent clearance process; and
- a grant to each brand company of 12 years of marketing exclusivity following the brand approval.

Furthermore, the regulatory pathway creates the risk that the brand 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 brand 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 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 2016 or future years. 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 name brand drug or reference product. If our generic or biosimilar products are not substitutable at the pharmacy level for their corresponding name brand drug or 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 brand 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 drug 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 brand product. Should this occur with respect to one of our generic 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, brand pharmaceutical companies are lobbying state legislatures to enact physician prescription requirements, or in the absence of a prescription, physician and patient notification requirements, special labeling requirements and alternative naming requirements which if enacted could create barriers to substitution and adoption rates of interchangeable biologics as well as biosimilars. Should this occur with respect to one of our biosimilars or interchangeable biologic product candidates, it could materially reduce sales in those states which would substantially harm our business.

If our nonclinical studies and clinical trials for our novel product candidates, including necuparanib, 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 drug development candidates are safe and effective. Nonclinical studies and clinical trials of new development candidates are lengthy and expensive and the historical failure rate for development 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 necuparanib or our other drug 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 drug 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 development candidate and in initial human clinical studies of a development 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 necuparanib or our other 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 drug 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 products or potential products. 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 drugs or biological products we develop will be subject to ongoing regulatory review, including the review of clinical results which 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. 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 drug 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 as CMS and private payers determine whether or not to apply generic drug reimbursement approaches to reimbursement or to develop alternative approaches under Medicare, Medicaid and private insurance coverage. For example, under Medicare Part B, the assignment of reimbursement codes to a reference drug product and its generic equivalent creates a strong incentive for generic conversion. CMS has proposed to group all non-interchangeable biosimilars of a reference biologic under a single, separate reimbursement code from the code for the reference biologic. CMS has not determined that interchangeable biologic products should be under the same reimbursement code as their reference biologics. If separate codes are instituted, the value of interchangeability could be reduced or significantly impaired. Reimbursement uncertainty could adversely impact market acceptance of biosimilar products.

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

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

The Medicare Modernization Act of 2003, or MMA, changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for drugs that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for drug purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered drugs, and provides authority for limiting the number of drugs that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered drugs. As a result of the MMA and the expansion of federal coverage of drug 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 drug 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, health care 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 drugs sold into the Medicaid program, an extension of the rebate requirement to drugs used in risk-based Medicaid managed care plans, an extension of mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities, and discounts and fees applicable to brand-name drugs. 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.

Additionally, the BPCI Act establishes an abbreviated regulatory pathway for the approval of biosimilars and provides that brand biologic 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 brand 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 financial impact of this United States health care reform legislation over the next few years will depend on a number of factors, including but not limited to the issuance of implementation regulations and guidance and changes in sales volumes for products eligible for the new system of rebates, discounts and fees.

The full effects of the United States health care 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. Consequently, there is uncertainty regarding implementation of the new legislation.

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 applications for M356 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 applications and supplements may be subject to significant delays during their review cycles.

Risks Relating to Patents and Licenses

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 become involved in opposition, derivation, reexamination, *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. For example, two 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. Patent and Trademark Office 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.

While the United States Court of Appeals for the Federal Circuit ruled that the practice of our patented commercial manufacturing test by Amphaster did not fall within the scope of the safe harbor from patent infringement under federal patent law, 35 USC section 271(e)(1), Amphastar may challenge the ruling and there may remain uncertainty in the future regarding enforcement of our patents protecting manufacturing test methods. Additional information about this litigation is set forth under Part II, Item 3 " *Legal Proceedings* "in this Annual Report on Form 10-K. The uncertainty regarding the scope of the safe harbor may impair our ability to enforce certain of our patent rights and reduce the likelihood of enforcing certain of our patent rights to protect our innovations and our products. Accordingly, we do not know the degree of future enforceability for some of our proprietary rights.

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 fails to adequately perform under this collaboration, or if we or Sandoz terminate all or a portion of this collaboration, the development and commercialization of some of our products and product candidates, including GLATOPA and M356, would be impacted, delayed or terminated and our business would be adversely affected.

2006 Sandoz Collaboration Agreement

Either we or Sandoz 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 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 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 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 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 terminates due to our uncured breach or bankruptcy, Sandoz 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 to successfully continue to commercialize GLATOPA and are significantly dependent on Sandoz to successfully commercialize M356. We do not fully control Sandoz' 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' interests may differ or conflict from time-to-time or we may disagree with Sandoz' level of effort or resource allocation. Sandoz may internally prioritize our products 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 Baxalta Collaboration Agreement is important to our business. If we or Baxalta fail to adequately perform under the Agreement, or if we or Baxalta terminate the Agreement, the development and commercialization of our lead biosimilar, M923, would be delayed or terminated and our business would be adversely affected.

The Baxalta Collaboration Agreement may be terminated:

- by either party for breach by or bankruptcy of the other party;
- by Baxalta for its convenience;
- by us in the event Baxalta does not exercise commercially reasonable efforts to commercialize M923 in the United States or other specified countries, provided, that we also have certain rights to directly commercialize M923, as opposed to terminating the Baxalta Collaboration Agreement, in event of such a breach by Baxalta; or
- by either party in the event there is a condition constituting force majeure for more than a certain consecutive number of days.

If the Baxalta Collaboration Agreement were terminated by Baxalta for convenience or if Baxalta elects to terminate the Baxalta Collaboration Agreement with respect to M923 in the specified time frame or if we terminate the Baxalta Collaboration Agreement for breach by Baxalta, while we would have the right to research, develop, manufacture or commercialize the terminated products or license a third party to do so, 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 M923. 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 any terminated products, which could have a material adverse effect on our business. If Baxalta terminates the Baxalta Collaboration Agreement due to our uncured breach, Baxalta would retain the exclusive right to commercialize M923 on a world-wide basis, subject to certain payment obligations to us as outlined in the Agreement. In addition, depending upon the timing of the termination, we would no longer have any influence over or input into the clinical development strategy or/and the commercialization strategy or/and the legal strategy of M923.

Under the Baxalta Collaboration Agreement, we are dependent upon Baxalta to successfully conduct clinical trials for, and if approved, commercialize M923. We do not control Baxalta's administration of the clinical trials, commercialization activities or the resources it allocates to M923. Our interests and Baxalta's interests may differ or conflict from time to time, or we may disagree with Baxalta's level of effort or resource allocation. Baxalta may internally prioritize M923 differently than we do or it may not allocate sufficient resources to effectively or optimally administer clinical trials for, or commercialize, M923. If these events were to occur, our business would be adversely affected.

The Mylan Collaboration Agreement is important to our business. If we or Mylan fail to adequately perform under the Agreement, or if we or Mylan terminate the 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 was 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 was 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 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 and our collaborative partners depend on third parties for the manufacture of products. If we encounter difficulties in our supply or manufacturing arrangements, our business may be materially adversely affected.

We have a limited number of personnel with experience in, and we do not own facilities for, manufacturing products. In addition, we do not have, and do not intend to develop, the ability to manufacture material for our clinical trials or at commercial scale. To develop our product candidates, apply for regulatory approvals and commercialize any products, we or our collaborative partners need to contract for or otherwise arrange for the necessary manufacturing facilities and capabilities. In order to generate revenue from the sales of Enoxaparin Sodium Injection and GLATOPA, sufficient quantities of such product must also be produced in order to satisfy demand. If these contract manufacturers are unable to manufacture sufficient quantities of product, comply with regulatory requirements, or breach or terminate their manufacturing arrangements with us, the development and commercialization of the affected products or drug candidates could be delayed, which could have a material adverse effect on our business. In addition, any change in these manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and the expenses relating to the transfer of necessary technology and processes could be significant.

We have relied upon third parties 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 products or market them.

In addition, 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 our failure to scale-up our 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 drug candidates 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.

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 senior executive management within, or a change in control of Sandoz, Baxalta or Mylan, 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 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, or 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 allocated to support our programs. For example, in January 2016, Baxalta and Shire plc announced an agreement under which Shire will combine with Baxalta, subject to shareholder and regulatory approvals. Following such combination, we will become dependent on Shire plc to allocate resources for future development and commercialization of M923, and there could be changes or delays in the timing of the M923 program in connection with the integration of Baxalta and Shire plc. 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 prohibits 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 to sustain profitable sales or market share that meet expectations of securities analysts;
- other adverse FDA decisions relating to our GLATOPA or M356 programs, including an FDA decision to require additional data, including requiring clinical trials, as a condition to M356 ANDA approval;
- litigation involving our company or our general industry or both, including litigation pertaining to the launch of our, our collaborative partners' or our competitors' products;
- 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 Amphastar or others in the anti-trust suits 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 development 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, biosimilarity or interchangeability with respect to our technology-enabled generic product candidates or biosimilars;
- 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 biotech company securities specifically.

If any of these factors causes 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 extreme 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 these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. We may be the target of similar litigation in the future. Securities litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

As of February 5, 2016, pursuant to our sublease agreements, we lease a total of approximately 183,500 square feet of office and laboratory space in Cambridge, Massachusetts:

Property Location	Approximate Square Footage	Use	Lease Expiration Date
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
	183,500		

Item 3. LEGAL PROCEEDINGS

M356-Related Proceedings

On September 10, 2014, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against us and Sandoz in the United States Federal District Court in the District of Delaware in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for M356. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and seeks declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents. In April 2015, Teva and Yeda filed an additional suit against us and Sandoz in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in March 2015 and expires in 2030. In May 2015, this suit was consolidated with the initial suit filed in September 2014. In November 2015, Teva and Yeda filed a suit against us and Sandoz in the United States District Court for the District of Delaware alleging infringement related to a fourth Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in October 2015 and expires in 2030. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of M356 until the expiration of this patent. In December 2015, this suit was consolidated with the initial suit filed in September 2014. We and Sandoz have asserted various defenses and filed counterclaims for declaratory judgments of non-infringement, invalidity and unenforceability of the COPAXONE 40 mg/mL patents. A pre-trial claim construction hearing was held in February 2016 and the trial is scheduled to begin in September 2016.

M834-Related Proceedings

On July 2, 2015, we filed a petition for Inter Partes Review, or IPR, with the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, to challenge the validity of U.S. Patent No 8,476,239, a patent for ORENCIA owned by Bristol Myers Squibb (BMS). The PTAB issued a decision instituting the IPR proceedings in January 2016, and BMS filed for a rehearing by the full PTAB. Briefings by the parties will take place in 2016, with oral arguments scheduled for September 2016. A final opinion from the PTAB is expected in January 2017.

Enoxaparin Sodium Injection-Related Proceedings

On September 21, 2011, we and Sandoz sued Amphastar, International Medical Systems, Ltd., a wholly owned subsidiary of Amphastar and, together with Amphastar ("Amphastar") and Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), or 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 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 and in June 2013 the Supreme Court denied the petition.

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.

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. Amphastar has filed motions to increase the amount of the security bond, which we and Sandoz have opposed. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz will prevail in this patent enforcement suit.

On September 17, 2015, Amphastar filed a complaint against us and Sandoz in the United States District Court for the Central District of California. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz sought to prevent Amphastar from selling generic enoxaparin sodium injection and thereby exclude competition for generic enoxaparin sodium injection in violation of federal and California anti-trust laws and California unfair business laws. Amphastar is seeking unspecified damages and fees. In December 2015, we and Sandoz filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting that court to reverse and review the District Court's grant of transfer. While the outcome of litigation is inherently uncertain, we believe this suit is without merit, and we intend to vigorously defend ourself in this litigation.

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital ("NGH") filed a class action suit against us and Sandoz in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic enoxaparin sodium injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz sought to prevent Amphastar from selling generic enoxaparin sodium injection and thereby exclude competition for generic enoxaparin sodium injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, we and Sandoz filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. These motions are pending before the court. While the outcome of litigation is inherently uncertain, we believe this suit is without merit, and we intend to vigorously defend ourself 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 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 Market:

Quarter ended	High	Low
March 31, 2014	$ 19.90	$ 11.26
June 30, 2014	13.91	9.85
September 30, 2014	12.55	10.40
December 31, 2014	13.10	9.38
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

Holders

On February 22, 2016, 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

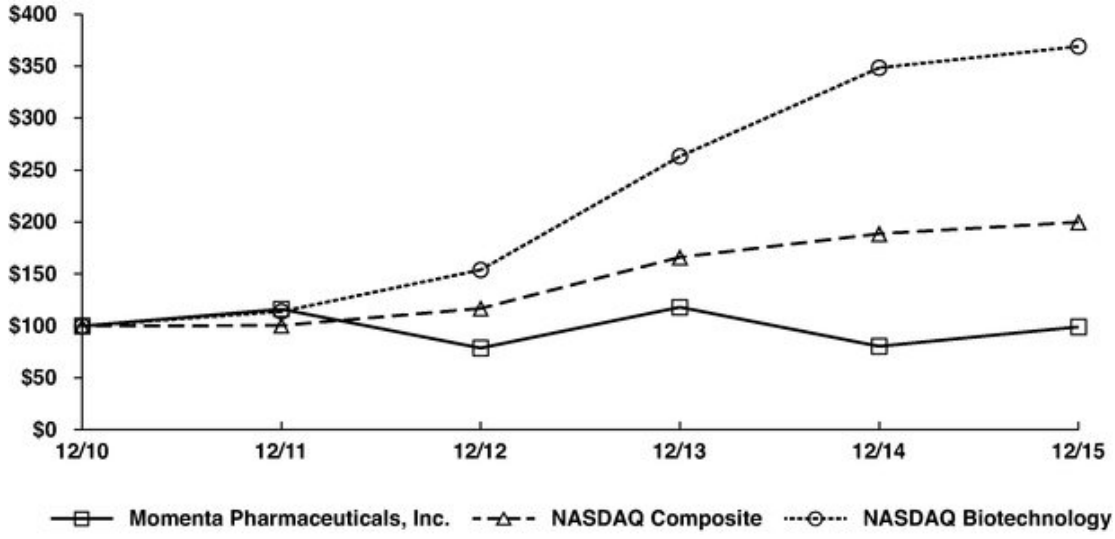
Information relating to compensation plans under which our equity securities are authorized for issuance is set forth in Item 12 below.

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, 2010 through December 31, 2015, 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 12/31/10 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	12/10	12/11	12/12	12/13	12/14	12/15
Momenta Pharmaceuticals, Inc .	**100.00**	**116.17**	**78.76**	**118.10**	**80.43**	**99.13**
NASDAQ Composite	**100.00**	**100.53**	**116.92**	**166.19**	**188.78**	**199.95**
NASDAQ Biotechnology	**100.00**	**113.92**	**153.97**	**263.29**	**348.49**	**369.06**

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 comprehensive loss data for the years ended December 31, 2015, 2014 and 2013 and the balance sheet data as of December 31, 2015 and 2014 are derived from our audited financial statements included in this Annual Report on Form 10-K. The statements of comprehensive income data for the years ended December 31, 2012 and 2011 and the balance sheet data as of December 31, 2013, 2012 and 2011 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) income 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

	2015	2014	2013	2012	2011
	(in thousands, except per share information)				
Statements of Comprehensive (Loss) Income Data:					
Collaboration revenues:					
Product revenue	$ 48,503	$ 19,963	$ 16,701	$ 54,772	$ 270,473
Research and development revenue	41,147	32,287	18,764	9,149	12,595
Total collaboration revenue	89,650	52,250	35,465	63,921	283,068
Operating expenses:					
Research and development	126,033	106,482	103,999	80,345	64,657
General and administrative	48,051	45,164	41,057	43,682	38,710
Total operating expenses	174,084	151,646	145,056	124,027	103,367
Operating (loss) income	(84,434)	(99,396)	(109,591)	(60,106)	179,701
Interest income	808	548	950	1,238	746
Interest expense	—	—	—	—	(91)
Other income	313	248	233	220	—
Net (loss) income	$ (83,313)	$ (98,600)	$ (108,408)	$ (58,648)	$ 180,356
Net (loss) income per share:					
Basic	$ (1.32)	$ (1.91)	$ (2.13)	$ (1.16)	$ 3.62
Diluted	$ (1.32)	$ (1.91)	$ (2.13)	$ (1.16)	$ 3.55
Shares used in calculating net (loss) income per share:					
Basic	63,130	51,664	50,907	50,411	49,852
Diluted	63,130	51,664	50,907	50,411	50,823
Comprehensive (loss) income	$ (83,293)	$ (98,641)	$ (108,494)	$ (58,456)	$ 180,291

	As of December 31,				
	2015	2014	2013	2012	2011
Balance Sheet Data:					
Cash and cash equivalents	$ 61,461	$ 61,349	$ 29,766	$ 52,990	$ 49,245
Marketable securities	288,583	130,180	215,916	287,613	299,193
Working capital	335,926	181,541	243,649	339,006	383,393
Total assets	421,040	256,216	316,815	406,629	420,909
Deferred revenue	21,983	30,998	27,716	31,695	3,764
Other liabilities	29,081	18,850	19,262	14,447	14,067
Total liabilities	51,064	49,848	46,978	46,142	17,831
Accumulated deficit	(452,372)	(369,059)	(270,459)	(162,051)	(103,403)
Total stockholders' equity	369,976	206,368	269,837	360,487	403,078

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 oncology and 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, 2015, we had an accumulated deficit of approximately $452 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—Mylan Collaboration Agreement

On January 8, 2016, we and Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., or Mylan, 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 world-wide basis, to develop, manufacture and commercialize six of our biosimilar candidates, including M834.

Under the terms of the Mylan Collaboration Agreement, Mylan has agreed to pay us a non-refundable upfront payment of $45 million. In addition, we and Mylan will share equally costs (including development, manufacturing, commercialization and certain legal expenses) and profits (losses) across the six product candidates.

Complex Generics

GLATOPA®—Generic 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 is the first "AP" rated, substitutable generic equivalent of once-daily COPAXONE. Sandoz commenced sales of GLATOPA on June 18, 2015. Under our collaboration agreement with Sandoz, we earn 50% of contractually-defined profits on GLATOPA sales. For the year ended December 31, 2015, we recorded $43.4 million in product revenues from Sandoz' sales of GLATOPA, reflecting $52.5 million in profit share net of a deduction of $9.1 million for reimbursement to Sandoz of 50% of pre-launch GLATOPA-related legal expenses incurred by Sandoz since 2008.

GLATOPA was formerly referred to as M356. M356 now refers to our generic product candidate for three-times-weekly COPAXONE 40 mg/mL.

M356—Generic Three-times-weekly COPAXONE® (glatiramer acetate injection) 40 mg/mL

An ANDA with a Paragraph IV certification for our generic version of three-times-weekly COPAXONE 40 mg/mL, which was filed in February 2014, remains under review by the FDA. Our M356 formulation contains the same drug substance as GLATOPA, 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 approved active pharmaceutical ingredient. If we are successful in our challenge of the patents related to 40 mg/mL COPAXONE, and based on the scheduled September 2016 trial start date and assuming customary patent litigation timelines, we believe M356 could be approved, following expiration of any 30-month stay, if applicable, and be on the market as early as the first quarter of 2017. In August 2015, the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, instituted an Inter Partes Review, or IPR, filed by a third party challenging the validity of several of the same patents relating to 40 mg/mL COPAXONE that are the subject of our patent litigation. We believe the outcome of this IPR could also impact our M356 litigation and launch timelines.

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.

Excluding contractual adjustments under our collaboration agreement, revenue earned on Enoxaparin Sodium Injection decreased from $20.0 million in 2014 to $6.9 million in 2015 on Sandoz' net sales of $197 million and $113 million, respectively, for those years. 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

M923—Biosimilar HUMIRA® (adalimumab) Candidate

In connection with Baxter's internal corporate restructuring in July 2015, Baxter assigned all of its rights and obligations under the Baxter Collaboration Agreement to Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated (collectively, "Baxalta"). In light of the assignment, all references to "Baxter" and the "Baxter Collaboration Agreement" have been replaced with references to "Baxalta" and the "Baxalta Collaboration Agreement," respectively. In January 2016, Baxalta and Shire plc announced an agreement under which Shire will combine with Baxalta, subject to shareholder and regulatory approvals.

In February 2015, Baxalta commenced a randomized, double-blind, single-dose study 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, Baxalta initiated a pivotal clinical trial in patients with chronic plaque psoriasis for M923. The trial is a randomized, double blind, active control, multi-center, global study in patients with chronic plaque psoriasis to compare the safety, efficacy and immunogenicity of M923 with HUMIRA. Baxalta is planning to submit the first regulatory submission for marketing approval for M923 in 2017 and, subject to marketing approval and patent considerations, we expect first commercial launch to be as early as 2018.

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. We are in the final stages of preclinical and process development work and plan to initiate clinical trials for this program in mid-year 2016. 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 on the market for ORENCIA.

Other Biosimilar Candidates

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

As of December 31, 2015, we had over 100 employees working on our biosimilars programs. We maintain a state-of-the-art development facility for bioprocess manufacturing development and scale-up.

Novel Therapeutics

Necuparanib

In 2012, we initiated a Phase 1/2 clinical trial evaluating necuparanib in combination with ABRAXANE® (nab-paclitaxel) plus gemcitabine in patients with advanced metastatic pancreatic cancer. In October 2014, we successfully completed and reported top-line data from Part A, or Phase 1, of the trial, including determining a maximum tolerated dose of 5 mg/kg. In June 2015 at the American Society of Clinical Oncology annual meeting, we reported more mature data from Phase 1 which continued to show acceptable safety and tolerability and encouraging signals of activity, including the following:

- Adding necuparanib to ABRAXANE and gemcitabine did not appear to increase the toxicity profile associated with ABRAXANE and gemcitabine alone.

- Of the 24 patients who received at least one dose of necuparanib in combination with ABRAXANE plus gemcitabine, the median overall survival was 14.2 months. Also, within a subset of 16 patients who completed one cycle and had at least one scan on treatment, the median overall survival was 15.3 months.

- Of the 15 patients treated with necuparanib in combination with ABRAXANE plus gemcitabine that completed Cycle 1 and had at least one follow-up measurement for CA19.9 (a biomarker predictive of long-term outcome and treatment response in pancreatic cancer), 93% had a greater than 50% decrease from baseline, and 100% had a greater than 20% decrease from baseline.

We believe the safety data and early signals of activity are encouraging and that the 5 mg/kg dose has the potential to provide significantly higher levels of activity against multiple cancer targets than traditional anticoagulant heparins have achieved. We believe these results, combined with nonclinical data in other cancer models, and necuparanib's differentiated, multi-targeted mechanism of action, suggest the possibility of combining necuparanib with other chemotherapy and targeted therapy standards of care in a variety of other tumor types. We continue to collect data from Phase 1 of the trial and plan to publish and/or present updated results following the completion of the study.

We continue to enroll patients in Part B, or Phase 2, of the trial, to evaluate the antitumor activity of necuparanib in combination with ABRAXANE plus gemcitabine, versus ABRAXANE plus

gemcitabine alone. We expect data from this randomized trial to be available in the second half of 2017. Subject to successfully completing clinical trials and obtaining marketing approval, we believe necuparanib could be on the market in the 2020-2021 timeframe, or potentially earlier under Fast-Track Designation.

In June 2014, necuparanib received Orphan Drug Designation from the U.S. FDA for the treatment of pancreatic cancer. In December 2014, we received Fast-Track designation by the FDA for necuparanib as a first-line treatment in combination with ABRAXANE and gemcitabine in patients with metastatic pancreatic cancer.

Other Novel Therapeutic Programs

We are continuing to advance M281, our Anti-FcRn program, and M230, our SIF3 program. Our goal is to progress M281 and M230 into clinical development in mid-2016 and in 2017, respectively. We are currently identifying and pursuing potential collaboration opportunities to further develop and commercialize of our hsIVIg program.

We believe these early stage programs 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.

Equity Financings

In May 2015, we 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, we received aggregate net proceeds of approximately $148.4 million, after deducting underwriting discounts and commissions and other offering expenses. We intend to use these proceeds for general corporate purposes, including working capital.

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 previously filed with the Securities and Exchange Commission (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. We concluded sales under the 2014 ATM Agreement in April 2015. In the year ended December 31, 2014, we sold approximately 1.7 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, we sold approximately 3.8 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately $55.2 million. 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.

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. 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 ended December 31, 2015, we sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement, raising aggregate net proceeds of approximately $9.3 million.

Results of Operations

Comparison of Years Ended December 31, 2015, 2014 and 2013

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. 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.

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

Sandoz commenced sales of GLATOPA in the United States on June 18, 2015. We earn 50% of contractually-defined profits on Sandoz' sales of GLATOPA. 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.

For the year ended December 31, 2015, we recorded $43.4 million in product revenues from Sandoz' sales of GLATOPA, reflecting $52.5 million in profit share net of a deduction of $9.1 million for reimbursement to Sandoz of 50% of pre-launch GLATOPA-related legal expenses incurred by Sandoz since 2008. We expect that any future quarterly legal expense deductions will be significantly less as they will generally be incurred and reimbursed on a quarterly basis. We estimate that the number of prescriptions for GLATOPA represents approximately 30% of the once-daily 20 mg/mL U.S. glatiramer acetate market.

We believe there is a meaningful market opportunity for GLATOPA. The price for COPAXONE 20 mg/mL has increased over 165% since 2009 and there is no other generic for multiple sclerosis currently available in the United States. However, 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 more than 70% of the overall U.S. glatiramer acetate market (20 mg/mL and 40mg/mL). Because GLATOPA is only a substitutable generic version of the 20 mg/mL formulation of COPAXONE, the market potential of GLATOPA is negatively impacted by the conversion of patients from once-daily COPAXONE to three-times-weekly COPAXONE. Teva reported $4.0 billion in worldwide sales of COPAXONE (20 mg/mL and 40 mg/mL) in 2015, $3.2 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. For the year ended December 31, 2015, we earned $5.1 million in product revenue consisting of $6.9 million in 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' reported net sales of Enoxaparin Sodium Injection of $113 million. 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' reported net sales of Enoxaparin Sodium Injection of $197 million, 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.

For the year ended December 31, 2013, we earned $16.7 million in product revenue, which consists of $20.5 million in royalties on Sandoz' reported net sales of Enoxaparin Sodium Injection of $213 million, offset by $3.8 million of our contractual share of development and other expenses for the product year ended June 30, 2013.

The decrease in our product revenue was $14.8 million, or 74%, from the 2014 period to the 2015 period. The amount of the decrease attributed to the change in our collaboration economics is approximately $4.5 million. In addition, product revenue in 2014 was increased by $2.1 million to reflect an adjustment to royalties earned in the product year ended June 30, 2012. The decrease in Sandoz' net sales of $84 million, or 43%, from the 2014 period to the 2015 period was due to 38% lower unit sales driven by lower market share and 7% lower prices in response to competitor pricing reductions on enoxaparin. The increase in our product revenue of $3.2 million, or 19%, from the 2013 period to the 2014 period is due to the $2.1 million adjustment to royalties earned as well as a lower annual claw-back adjustment in 2014.

Due to increased generic competition and resulting deceased 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;
- Reimbursement of research and development services and reimbursement of development costs under our collaborative arrangements; and
- Amortization of the equity premium (2006 Sandoz Collaboration Agreement) and amortization of the arrangement consideration (Baxalta Collaboration Agreement).

Research and development revenue for 2015 was $41.1 million, compared with $32.3 million for 2014 and $18.8 million for 2013. The increase in research and development revenue of $8.8 million, or 27%, from the 2014 period to the 2015 period includes an increase of $20.0 million for 2015 milestone payments we earned upon receiving sole FDA approval for GLATOPA and upon first commercial sale of GLATOPA. This increase is partially offset by a decrease of $12.0 million reflecting milestone payments we earned in 2014 upon achieving technical development criteria for M923 under the Baxalta Collaboration Agreement. The increase in research and development revenue of $13.5 million, or 72%, from the 2013 period to the 2014 period is primarily due to $12.0 million earned by us in 2014 for the achievement of M923 technical development milestones under the Baxalta Collaboration Agreement.

We expect collaborative research and development revenue earned by us related to FTE and external expense reimbursement from Baxalta and Sandoz will fluctuate from quarter to quarter in 2016 depending on our research and development activities. Furthermore, we expect to continue to amortize the $40 million arrangement consideration from Baxalta as we deliver research and development services under the collaboration agreement, with anticipated 2016 quarterly amortization of approximately $2.4 million related to M923.

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.

Research and development expense for 2015 was $126.0 million, compared with $106.5 million in 2014 and $104.0 million in 2013. 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 approval of the GLATOPA 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 GLATOPA ANDA approval, which occurred in April 2015. 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 increase in research and development expense of $2.5 million, or 2%, from the 2013 period to the 2014 period resulted from increases of: $2.7 million in rent and facility-related costs due to additional subleased laboratory and office space; $2.5 million in costs to purchase antibodies to be used in our novel therapeutics research program; $2.1 million in personnel-related expenses associated with

our annual merit salary increase and grants of stock options and stock awards; $1.9 million in necuparanib clinical costs incurred to complete the Phase 1 clinical trial as well as start-up and patient enrollment costs incurred for the Phase 2 trial; $1.0 million in laboratory supplies to support our product candidates; and $0.2 million in depreciation expense due to higher capital investments. These increases were partially offset by decreases of: $5.8 million primarily related to lower third-party process development and contract research costs incurred for M923; $1.8 million in consulting fees related to our biosimilars business activities; and $0.3 million in travel-related expenses to support our portfolio.

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, 2015, 2014 and 2013. 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. Certain prior period amounts have been reclassified to conform to the current period presentation.

	Phase of Development as of December 31, 2015	Year Ended December 31,			Project Inception to December 31, 2015
		2015	2014	2013	
External Costs Incurred by Product Candidate:					
GLATOPA and M356—Generic COPAXONE® (20 mg/mL and 40 mg/mL)	ANDAs filed(1)	$ 856	$ 920	$ 2,525	$ 48,863
Necuparanib—Oncology Product Candidate	Phase 2	11,801	6,739	3,930	36,875
Biosimilars	Various(2)	23,605	19,583	24,501	79,127
Other novel therapeutic programs	Discovery/Nonclinical	15,999	5,213	3,298	
Internal Costs		73,772	74,027	69,745	
Total Research and Development Expenses		$ 126,033	$ 106,482	$ 103,999	

(1) On April 16, 2015, the FDA approved the ANDA for once-daily GLATOPA. Sandoz launched GLATOPA on June 18, 2015. The ANDA for M356 is under FDA review.

(2) Biosimilars includes M923, a biosimilar version of HUMIRA® (adalimumab), M834, a biosimilar version of ORENCIA® (abatacept), as well as seven other biosimilar candidates. A pivotal clinical trial for M923 commenced in October 2015. M834 is in the nonclinical phase of development, and our other biosimilar candidates are in discovery and process development.

Our necuparanib external expenditures increased by $5.1 million, or 75%, from the 2014 period to the 2015 period as the latter period includes ongoing patient costs for the Phase 1 clinical trial as well as contract research and site and patient costs for Phase 2 of the Phase 1/2 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 is responsible for clinical development. 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 $1.6 million in GLATOPA and M356 external expenditures from the 2013 period to the 2014 period was due to lower process development activities, manufacturing and third-party costs. Our necuparanib external expenditures increased by $2.8 million from the 2013 period to the 2014 period as we completed Part A of the Phase 1/2 trial and entered Phase 2 of the trial during the fourth quarter of 2014. The decrease of $4.9 million in biosimilars external expenditures from the 2013 period to the 2014 period was due to lower third-party process development and contract research costs incurred for our biosimilars in development. The increase of $1.9 million in other novel therapeutics program external expenditures from the 2013 period to the 2014 period was primarily due to increased expenditures to support development of product candidates.

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* ". The increase of $4.3 million from the 2013 period to the 2014 period was due to additional research and development headcount and related costs in support of our development programs.

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.

General and administrative expense for 2015 was $48.1 million, compared with $45.2 million in 2014 and $41.1 million in 2013. 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".

The increase in general and administrative expense of $4.1 million, or 10%, from the 2013 period to the 2014 period was due to increases of: $1.1 million in allocated rent and facility-related costs due to additional subleased laboratory and office space; $1.3 million in personnel-related expenses associated with our annual merit salary increase and grants of stock options and stock awards; $0.6 million in allocated lab supplies, $0.4 million in professional fees, driven mainly by increased IT infrastructure and tax-related accounting fees; $0.3 million in allocated depreciation expense due to higher capital investments; and $0.2 million in other fees.

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 $0.8 million, $0.5 million and $1.0 million for the years ended December 31, 2015, 2014 and 2013, respectively. The increase of $0.3 million from the 2014 period to the 2015 period was caused by higher average investment balances due to 2015 fundraising activities. The decrease of $0.5 million from the 2013 period to the 2014 period was primarily due to lower average investment balances.

Other Income

We recognized one-fifth of a job creation tax award, or $0.2 million, as other income in each of the years ended December 31, 2015, 2014 and 2013.

Liquidity and Capital Resources

At December 31, 2015, we had $350 million in cash, cash equivalents and marketable securities and $19.4 million in accounts receivable, including $15.6 million for fourth quarter 2015 GLATOPA sales and $2.2 million for fourth quarter 2015 Enoxaparin Sodium Injection sales. In addition, we also held $20.7 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, 2015 were primarily invested in senior debt of government-sponsored enterprises, 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 24 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, 2015.

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. Since our inception through December 31, 2015, 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 with Stifel, Nicolaus & Company, Incorporated entered into in May 2014 and April 2015 (the "ATM Agreements"). As of December 31, 2015, we had received a cumulative total of $659 million under our collaborations with Sandoz, including $469 million in revenues on sales of Enoxaparin Sodium Injection and regulatory and commercial milestones related to that product and $63 million in revenues on sales of GLATOPA and regulatory and commercial milestones related to that product. In addition, we received $83 million under our collaboration with Baxalta, including a $33 million upfront payment,

$31 million in reimbursement of research and development services and costs and $19 million in license and milestone payments. In the first quarter of 2016, we expect to receive a $45 million upfront payment from Mylan and, in addition to the upfront payment, in 2016 we expect to receive $60 million of the total $200 million in early development milestone payments from Mylan under our collaboration with Mylan.

We expect to finance and manage our planned operating and expenditure requirements principally through our current cash, cash equivalents and marketable securities; capital raised through equity financings, including under our ATM Agreements; and future product revenues. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2018.

	Year Ended December 31,		
	2015	2014	2013
	(in thousands)		
Net cash used in operating activities	$ (71,515)	$ (65,168)	$ (86,832)
Net cash (used in) provided by investing activities	$ (163,834)	$ 75,173	$ 58,586
Net cash provided by financing activities	$ 235,461	$ 21,578	$ 5,022
Net increase (decrease) in cash and cash equivalents	$ 112	$ 31,583	$ (23,224)

Cash 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 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. In addition, the net change in our operating assets and liabilities used cash of $9.7 million and resulted from: an increase in accounts receivable of $12.0 million, which includes receivables totaling $17.8 million for fourth quarter 2015 GLATOPA and Enoxaparin Sodium Injection product revenues and the collection of a $4.7 million receivable for fourth quarter 2014 Enoxaparin Sodium Injection royalties; a decrease in unbilled revenue of $1.1 million primarily due to lower reimbursable FTEs and external costs for M923; a decrease in accounts payable of $3.4 million due to timing of vendor payments; an increase in accrued expenses of $14.2 million primarily due to process development services for our biosimilars and novel therapeutics programs; a decrease in deferred revenue of $9.0 million, due to higher quarterly amortization of revenue from the $40 million arrangement consideration from Baxalta; and a decrease in other long-term liabilities of $0.5 million, of which $0.2 million is the annual amortization of a job creation tax award and $0.3 million is the amortization of the tenant improvement allowance over the term of the facility lease.

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. In addition, the net change in our operating assets and liabilities provided cash of $9.0 million and resulted from: decreases in accounts receivable and unbilled revenue totaling $6.2 million due to lower reimbursable FTEs and costs for M923 as M923 entered the clinic in late 2014 (under the Baxalta Collaboration Agreement, Baxalta has responsibility for all clinical development and associated clinical costs once a biosimilar enters the clinic); an increase in accounts payable of $1.1 million due to timing of vendor payments; a decrease in accrued expenses of $1.1 million due to lower legal fees, lower compensation-based accruals, and lower process development and contract research costs for M923; an increase in deferred revenue of $3.3 million, which includes

an increase related to the $7.0 million M834 license payment from Baxalta partially offset by amortization of $3.2 million of revenue from the $40 million arrangement consideration from Baxalta and $0.5 million of revenue from the Sandoz equity premium; and a decrease in other long-term liabilities of $0.5 million, of which $0.2 million is the annual amortization of a job creation tax award and $0.3 million is the amortization of the tenant improvement allowance over the term of the facility lease.

Cash used in operating activities was $86.8 million for the year ended December 31, 2013 reflecting a net loss of $108.4 million, which was partially offset by non-cash charges of $8.2 million for depreciation and amortization of property, equipment and intangible assets, $12.8 million for share-based compensation and $3.6 million for amortization of purchased premiums on our marketable securities. In addition, the net change in our operating assets and liabilities used cash of $3.3 million and resulted from: an increase in accounts receivable of $2.3 million due to an increase in reimbursable M923 FTEs and expenses incurred in connection with the Baxalta Collaboration Agreement offset by lower Enoxaparin Sodium Injection product revenue due to aggressive competitor pricing reductions; an increase in unbilled revenue of $2.6 million, primarily due to an increase in reimbursable M923 FTEs and expenses incurred in connection with the Baxalta Collaboration Agreement; a decrease in prepaid expenses and other current assets of $1.6 million, primarily due to the receipt of a $1.1 million job creation tax award and the receipt of a $0.4 million security deposit related to subleased office and laboratory space; an increase in restricted cash of $0.7 million due to the designation of this cash as collateral for a letter of credit related to the lease of office and laboratory space at 320 Bent Street; an increase in accounts payable of $2.7 million due to timing of M923 expenses incurred; an increase in accrued expenses of $1.8 million due to higher compensation-related accruals due to increased staffing levels; a decrease in deferred revenue of $4.0 million, primarily due to the amortization of revenue from the $33.0 million Baxalta upfront payment; and an increase in other long-term liabilities of $0.3 million driven by the receipt of $0.7 million from our landlord for leasehold improvements constructed to our leased space at 320 Bent Street and partially offset by $0.3 million in amortization of the tenant improvement allowance over the term of our facility lease and $0.2 million in amortization of a job creation tax award.

Cash (used in) provided by investing activities

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 investing activities of $58.6 million for the year ended December 31, 2013 includes cash inflows of $294.2 million from maturities of marketable securities and $3.8 million from sales of marketable securities, offset by cash outflows of $230.0 million for purchases of marketable securities and $9.5 million for capital equipment and leasehold improvements.

Cash provided by financing activities

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.

Cash provided by financing activities of $5.0 million for the year ended December 31, 2013 consists solely of 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, purchase commitments to a contractual research and manufacturing organization as well as operating lease obligations.

During the three months ended December 31, 2015, we entered into purchase commitments for approximately $4.8 million related to analytical testing services for certain of our programs. We expect to pay the amounts related to the purchase commitments over the next four quarters. In the event we terminate the purchase commitment, we shall pay all amounts due for work performed by vendor through the termination date.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2015 (in thousands):

Contractual Obligations	Total	2016	2017 through 2018	2019 through 2020	After 2020
License maintenance obligations	$ 1,163	$ 233	$ 465	$ 465	*
Operating lease obligations	99,590	9,254	20,216	15,842	$ 54,278
Other non-cancelable contractual commitments	4,773	4,773	—	—	—
Total contractual obligations	$ 105,526	$ 14,260	$ 20,681	$ 16,307	$ 54,278

* After 2020, the annual obligations, which extend through the life of the patents are approximately $0.2 million per year.

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. 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 (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 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. 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, 2015 and December 31, 2014.

During the years ended December 31, 2015 and 2014, 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, 2015 and December 31, 2014. 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 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 2012, except to the extent that in the future we utilize net operating losses or tax credit carryforwards that originated before 2012.

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, 2015, 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, 2015 and 2014, and the related consolidated statements of comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. 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, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, 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, 2015, 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 26, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 26, 2016

MOMENTA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 61,461	$ 61,349
Marketable securities	288,583	130,180
Accounts receivable	19,385	7,427
Unbilled revenue	1,800	2,909
Prepaid expenses and other current assets	3,479	3,465
Total current assets	374,708	205,330
Property and equipment, net	21,896	25,422
Restricted cash	20,660	20,719
Intangible assets, net	3,528	4,589
Other long-term assets	248	156
Total assets	$ 421,040	$ 256,216
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,053	$ 7,433
Accrued expenses	24,499	10,348
Deferred revenue	9,770	5,490
Other current liabilities	460	518
Total current liabilities	38,782	23,789
Deferred revenue, net of current portion	12,213	25,508
Other long-term liabilities	69	551
Total liabilities	51,064	49,848
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Preferred stock, $0.01 par value per share; 5,000 shares authorized at December 31, 2015 and 2014, 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 at December 31, 2015 and 2014, 69,077 and 54,486 shares issued and outstanding at December 31, 2015 and 2014, respectively	7	5
Additional paid-in capital	824,385	575,438
Accumulated other comprehensive income (loss)	4	(16)
Accumulated deficit	(452,372)	(369,059)
Treasury stock, at cost, 119 shares and zero shares at December 31, 2015 and December 31, 2014, respectively	(2,048)	—
Total stockholders' equity	369,976	206,368
Total liabilities and stockholders' equity	$ 421,040	$ 256,216

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

MOMENTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share amounts)

	Year Ended December 31,		
	2015	2014	2013
Collaboration revenues:			
Product revenue	$ 48,503	$ 19,963	$ 16,701
Research and development revenue	41,147	32,287	18,764
Total collaboration revenue	89,650	52,250	35,465
Operating expenses:			
Research and development*	126,033	106,482	103,999
General and administrative*	48,051	45,164	41,057
Total operating expenses	174,084	151,646	145,056
Operating loss	(84,434)	(99,396)	(109,591)
Other income:			
Interest income	808	548	950
Other income	313	248	233
Total other income	1,121	796	1,183
Net loss	$ (83,313)	$ (98,600)	$ (108,408)
Net loss per share:			
Basic and diluted	$ (1.32)	$ (1.91)	$ (2.13)
Weighted average shares outstanding:			
Basic and diluted	63,130	51,664	50,907
Comprehensive loss:			
Net loss	$ (83,313)	$ (98,600)	$ (108,408)
Net unrealized holding gains (losses) on available-for-sale marketable securities	20	(41)	(86)
Comprehensive loss	$ (83,293)	$ (98,641)	$ (108,494)
* Non-cash share-based compensation expense included in operating expenses is as follows:			
Research and development	$ 5,145	$ 6,204	$ 5,520
General and administrative	$ 6,295	$ 7,390	$ 7,302

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

MOMENTA PHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Treasury Stock		Total Stockholders' Equity
	Shares	Par Value				Shares	Amount	
Balances at December 31, 2012	51,709	$ 5	$ 522,422	$ 111	$ (162,051)	—	$ —	$ 360,487
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	516	—	5,022	—	—	—	—	5,022
Issuance of restricted stock	172	—	—	—	—	—	—	—
Cancellation of restricted stock	(40)	—	—	—	—	—	—	—
Share-based compensation expense for employees	—	—	12,668	—	—	—	—	12,668
Share-based compensation expense for non-employees	—	—	154	—	—	—	—	154
Unrealized loss on marketable securities	—	—	—	(86)	—	—	—	(86)
Net loss	—	—	—	—	(108,408)	—	—	(108,408)
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 facility	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

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,		
	2015	2014	2013
Cash Flows from Operating Activities:			
Net loss	$ (83,313)	$ (98,600)	$ (108,408)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	7,594	7,637	7,108
Share-based compensation expense	11,440	13,594	12,822
Amortization of premium on investments	1,383	2,162	3,575
Amortization of intangibles	1,061	1,061	1,061
Impairment of equity investment	—	—	244
Loss on disposal of assets	—	—	23
Changes in operating assets and liabilities:			
Accounts receivable	(11,958)	5,668	(2,284)
Unbilled revenue	1,109	504	(2,613)
Prepaid expenses and other current assets	(14)	(64)	1,552
Restricted cash	59	—	(748)
Other long-term assets	(92)	—	—
Accounts payable	(3,380)	1,126	2,727
Accrued expenses	14,151	(1,099)	1,806
Deferred revenue	(9,015)	3,282	(3,979)
Other current liabilities	(58)	22	(18)
Other long-term liabilities	(482)	(461)	300
Net cash used in operating activities	(71,515)	(65,168)	(86,832)
Cash Flows from Investing Activities:			
Purchases of property and equipment	(4,068)	(8,360)	(9,450)
Purchases of marketable securities	(405,673)	(111,809)	(229,969)
Proceeds from maturities of marketable securities	245,907	195,342	294,183
Proceeds from sales of marketable securities	—	—	3,822
Net cash (used in) provided by investing activities	(163,834)	75,173	58,586
Cash Flows from Financing activities:			
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	24,567	3,273	5,022
Repurchase of common stock pursuant to share surrender	(2,048)	—	—
Net cash provided by financing activities	235,461	21,578	5,022
Increase (decrease) in cash and cash equivalents	112	31,583	(23,224)
Cash and cash equivalents, beginning of period	61,349	29,766	52,990
Cash and cash equivalents, end of period	$ 61,461	$ 61,349	$ 29,766

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 oncology and autoimmune disease. 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 and determinable; and collection is reasonably assured.

The Company enters into collaboration and license agreements for the development and commercialization of biosimilar products. 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 certain committees with the collaborators. Payments to the Company under these agreements may include nonrefundable upfront license fees, payments for research and development services and costs, payments based upon the achievement of defined collaboration objectives and profit share and/or royalties on product sales.

For revenue agreements with multiple-elements, the Company identifies the deliverables included within the agreement and evaluates which deliverables may represent separate units of accounting based on the achievement of certain criteria, including whether the delivered element 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) 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.

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. 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.

Upfront 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. Such payments are recognized as revenue over the estimated period of performance. The Company regularly reviews the estimated period of performance based on the progress made under each arrangement. Amounts received as funding of research and development activities are recognized as revenue when the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such development and related services.

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. Milestones are 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. The Company's 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 and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates 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-substantive contingent payments are classified as deferred revenue if they are ultimately expected to result in revenue recognition. The Company recognizes non-substantive contingent payments over the remaining estimated period of performance once the specific objective 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.

Profit share and/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. These amounts are determined based on amounts provided by the collaboration partner 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.

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, 2015 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, 2015, 2014 and 2013. There were no realized gains or losses on marketable securities during the years ended December 31, 2015 or 2014. Realized gains on marketable securities for the year ended December 31, 2013 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 carried at fair value, which approximates cost at December 31, 2015 and 2014.

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, 2015 and December 31, 2014.

The carrying amounts reflected in the Company's consolidated balance sheets for cash, accounts receivable, unbilled receivables, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

Concentration of Credit Risks

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

Accounts Receivable and Unbilled Revenue

Accounts receivable represents amounts due to the Company at December 31, 2015 from collaborators related to profit share due on net sales of Enoxaparin Sodium Injection and GLATOPA, as well as reimbursement of research and development services and external costs. Accounts receivable represents amounts due to the Company at December 31, 2014 from collaborators related to royalties due on net sales of Enoxaparin Sodium Injection and reimbursement of research and development services and external costs. Unbilled revenue represents amounts owed at December 31, 2015 and December 31, 2014 from collaborators for reimbursement of research and development services and external costs. The Company has not recorded any allowance for uncollectible accounts or bad debt write-offs and it monitors its receivables to facilitate timely payment.

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. 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 statement of income (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, 2015.

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 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 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, 2015 and 2014.

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 2012, except to the extent that in the future it utilizes net operating losses or tax credit carry forwards that originated before 2012. As of December 31, 2015, 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 (loss) income 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.

The following tables summarize the changes in accumulated other comprehensive income (loss) during the years ended December 31, 2015 and December 31, 2014 (in thousands):

	Unrealized Gains (Losses) on Securities Available for Sale
Balance as of January 1, 2015	$ (16)
Other comprehensive income before reclassifications	20
Amounts reclassified from accumulated other comprehensive income	—
Net current period other comprehensive income	20
Balance as of December 31, 2015	$ 4

	Unrealized Gains (Losses) on Securities Available for Sale
Balance as of January 1, 2014	$ 25
Other comprehensive income before reclassifications	(41)
Amounts reclassified from accumulated other comprehensive income	—
Net current period other comprehensive income	(41)
Balance as of December 31, 2014	$ (16)

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 oncology and 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

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 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. 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. The Company is currently evaluating the method of adoption and the potential impact that Topic 606 may 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 interim and annual periods after December 15, 2016, and will not have material impact on the consolidated financial statements, but may impact the Company's footnote disclosures.

In November 2015, the FASB issued ASU No. 2015-17, Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. The new standard requires that deferred tax assets and liabilities be classified as noncurrent in a classified statement of financial position. The Company will adopt ASU No. 2015-17 in 2016. The Company does not expect the adoption of this standard will have a material impact on its 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, 2015 and December 31, 2014, 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, 2015 and December 31, 2014 are summarized as follows (in thousands):

Description	Balance as of December 31, 2015	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds 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	—
Total	$ 342,660	$ 30,077	$ 312,583	$ —

Description	Balance as of December 31, 2014	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds	$ 55,283	$ 55,283	$ —	$ —
Corporate debt securities	980	—	980	—
Marketable securities:				
Corporate debt securities	70,668	—	70,668	—
Commercial paper obligations	15,250	—	15,250	—
Foreign government bonds	18,520	—	18,520	—
Asset-backed securities	25,742	—	25,742	—
Total	$ 186,443	$ 55,283	$ 131,160	$ —

As of December 31, 2015, the Company held $24.0 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. For the years ended December 31, 2015 and 2014, there were no transfers between Level 1 and Level 2 financial assets. The Company did not have any non-recurring fair value measurements on any assets or liabilities at December 31, 2015 and December 31, 2014.

4. Cash, Cash Equivalents and Marketable Securities

The following tables summarize the Company's cash, cash equivalents and marketable securities as of December 31, 2015 and December 31, 2014 (in thousands):

As of December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
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
Total	$ 350,040	$ 126	$ (122)	$ 350,044
Reported as:				
Cash and cash equivalents	$ 61,461	$ —	$ —	$ 61,461
Marketable securities	288,579	126	(122)	288,583
Total	$ 350,040	$ 126	$ (122)	$ 350,044

As of December 31, 2014	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 60,369	$ —	$ —	$ 60,369
Corporate debt securities due in one year or less	71,669	3	(24)	71,648
Commercial paper obligations due in one year or less	15,237	13	—	15,250
Foreign government bonds due in one year or less	18,519	2	(1)	18,520
Asset-backed securities due in one year or less	25,751	—	(9)	25,742
Total	$ 191,545	$ 18	$ (34)	$ 191,529
Reported as:				
Cash and cash equivalents	$ 61,349	$ —	$ —	$ 61,349
Marketable securities	130,196	18	(34)	130,180
Total	$ 191,545	$ 18	$ (34)	$ 191,529

At December 31, 2015 and December 31, 2014, the Company held 66 and 44 marketable securities, respectively, which were in a continuous unrealized loss position for less than one year. At December 31, 2015, there were no marketable securities in a continuous unrealized loss position for greater than one year. At December 31, 2014, there was one marketable security in a continuous unrealized loss position for greater than one year. The unrealized losses were caused by fluctuations in interest rates.

The following table summarizes the aggregate fair value of these securities at December 31, 2015 and December 31, 2014 (in thousands):

	As of December 31, 2015		As of December 31, 2014	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate debt securities due in one year or less	$ 70,657	$ (84)	$ 63,221	$ (24)
Commercial paper obligations due in one year or less	$ 33,734	$ (8)	$ —	$ —
Asset-backed securities due in one year or less	$ 61,337	$ (30)	$ 25,742	$ (9)
Foreign government bonds due in one year or less	$ —	$ —	$ 12,773	$ (1)

5. Property and Equipment

As of December 31, 2015 and December 31, 2014, property and equipment, net consists of the following (in thousands):

	2015	2014	Depreciable Lives
Computer equipment	$ 2,426	$ 2,005	3 years
Software	9,900	9,001	3 years
Office furniture and equipment	2,524	2,436	5 to 6 years
Laboratory equipment	43,286	40,626	7 years
Leasehold improvements	12,735	12,735	Shorter of asset life or lease term
Less: accumulated depreciation	(48,975)	(41,381)	
	$ 21,896	$ 25,422	

During 2015 and 2014, the Company disposed of laboratory equipment with total gross carrying amount of $0.3 million and $0.2 million, respectively, and accumulated depreciation of $0.3 million and $0.2 million, respectively. Depreciation and amortization expense amounted to $7.9 million, $7.6 million and $7.1 million for the years ended December 31, 2015, 2014 and 2013, respectively.

6. Intangible Assets

Intangible assets consist solely of core developed technology acquired as part of a 2007 asset purchase agreement with Parivid LLC. See Part I, Item 1 "*Business—Collaborations, Licenses and Asset Purchases—Parivid*" in this Annual Report on Form 10-K for relevant disclosures. The developed technology intangible assets are being amortized over the estimated useful life of the Enoxaparin Sodium Injection and GLATOPA developed technology of approximately 10 years. As of December 31, 2015 and December 31, 2014, intangible assets, net of accumulated amortization, are as follows (in thousands):

		2015		2014	
	Weighted-Average Amortization Period (in years)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Total intangible assets for core and developed technology and non-compete agreement	10	$ 10,427	$ (6,899)	$ 10,427	$ (5,838)

Amortization is computed using the straight-line method over the useful lives of the respective intangible assets as there is no other pattern of use that is reasonably estimable. Amortization expense was approximately $1.1 million in each of the years ended December 31, 2015, 2014 and 2013.

The Company expects to incur amortization expense of appropriately $1.1 million per year for each of the next three years (2016 to 2018) and $0.3 million in the fourth year (2019).

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 and, together with Amphastar ("Amphastar") and Actavis, 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 the remaining term of the lease which ends in April 2015 and will remain restricted during the extension period, which ends in April 2018. 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 the lease term and during any lease term extensions. The Company will earn interest on the balance.

8. Accrued Expenses

As of December 31, 2015 and December 31, 2014, accrued expenses consisted of the following (in thousands):

	2015	2014
Accrued compensation	$ 7,848	$ 6,912
Accrued contracted research costs	14,710	2,031
Accrued professional fees	1,354	828
Accrued royalties	19	165
Other	568	412
	$ 24,499	$ 10,348

9. Collaborations and License Agreements

The following tables provide amounts by year and by line item included in the Company's consolidated statements of 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, 2015 (in thousands)			
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Baxalta Collaboration Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 5,063	$ 43,440	$ —	$ 48,503
Research and development revenue:				
Milestone payments	—	20,000	—	20,000
Amortization 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(1)	$ 324	$ 856	$ 1,851	$ 3,031
General and administrative expense(1)	$ 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	Total Collaborations
Collaboration revenues:				
Product revenue	$ 19,963	$ —	$ —	$ 19,963
Research and development revenue:				
Milestone payments	—	—	12,000	12,000
Amortization 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
Total research and development revenue	$ 1,043	$ 2,932	$ 28,312	$ 32,287
Total collaboration revenues	$ 21,006	$ 2,932	$ 28,312	$ 52,250
Operating expenses:				
Research and development expense(1)	$ 341	$ 920	$ 16,637	$ 17,898
General and administrative expense(1)	$ 125	$ 299	$ 527	$ 951
Total operating expenses	$ 466	$ 1,219	$ 17,164	$ 18,849

	For the Year Ended December 31, 2013 (in thousands)			
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Baxalta Collaboration Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 16,701	$ —	$ —	$ 16,701
Research and development revenue:				
Amortization of upfront payments	—	1,128	2,851	3,979
Research and development services and external costs	3,040	715	11,030	14,785
Total research and development revenue	$ 3,040	$ 1,843	$ 13,881	$ 18,764
Total collaboration revenues	$ 19,741	$ 1,843	$ 13,881	$ 35,465
Operating expenses:				
Research and development expense(1)	$ 802	$ 2,525	$ 22,707	$ 26,034
General and administrative expense(1)	$ —	$ 511	$ 493	$ 1,004
Total operating expenses	$ 802	$ 3,036	$ 23,200	$ 27,038

(1) 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.

2003 Sandoz Collaboration Agreement

In 2003, the Company entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration Agreement, with Sandoz AG (formerly Sandoz N.V. and Biochemie West Indies, N.V.) and Sandoz Inc. (formerly Geneva Pharmaceuticals, Inc.) to jointly develop, manufacture and commercialize Enoxaparin Sodium Injection, a generic version of LOVENOX®, in the United States. Sandoz N.V. later assigned its rights in the 2003 Sandoz Collaboration Agreement to Sandoz AG, an affiliate of Novartis Pharma AG. The Company refers to Sandoz AG and Sandoz Inc. together as Sandoz.

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 our intellectual property rights to develop and commercialize injectable enoxaparin for all medical indications within the United States. The Company identified two significant deliverables in this arrangement consisting of: (i) the license and (ii) development and related services. The Company determined that the license did not meet the criteria for separation as it did not have stand-alone value apart from the development services, which are proprietary to the Company. Therefore, the Company determined that a single unit of accounting exists with respect to the 2003 Sandoz Collaboration Agreement.

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. See "Product revenue" in the tables above for product revenue earned by the Company in the years ended December 31, 2015, 2014 and 2013 on Sandoz' sales of Enoxaparin Sodium Injection.

The Company is no longer eligible to receive milestones under the 2003 Sandoz Collaboration Agreement because the remaining milestones were contingent upon there being no third-party competitors marketing an interchangeable generic version of LOVENOX.

The collaboration is governed by a joint steering committee and a joint project team, each consisting of an equal number of Sandoz and Company representatives. Most decisions must be made unanimously, with Sandoz collectively having one vote and the Company having one vote. Sandoz has the sole authority to determine the price at which it sells 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. 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 annual adjustment was approximately $1.8 million for the product year ended June 30, 2015 and was paid in full as of December 31, 2015. The annual adjustment of $2.2 million for the product year ended June 30, 2014 was decreased by $2.1 million to reflect an adjustment to royalties earned in the 2012 product year. The annual adjustment was $3.8 million for the product year ended June 30, 2013.

The Company is reimbursed at a contractual FTE rate for any full-time equivalent 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. See "Research and development revenue" in the tables above for research and development revenue earned by the Company under the 2003 Sandoz Collaboration Agreement.

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, or Sandoz; and a stock purchase agreement and an investor rights agreement, with Novartis Pharma AG, or Novartis. Under the 2006 Sandoz Collaboration Agreement, the Company and Sandoz agreed to exclusively collaborate on the development and commercialization of COPAXONE and M356, 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 and M356, the Company is generally responsible for all of the development costs in the United States. For GLATOPA and M356 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 full-time equivalent employee expenses as well as any external costs incurred in the development of products to the extent development costs are born by Sandoz. All commercialization costs are borne by Sandoz.

Sandoz commenced sales of GLATOPA 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. The Company is entitled to earn 50% of contractually-defined profits on Sandoz' worldwide net sales of M356, if and when M356 is commercialized. Profits on net sales of GLATOPA and M356 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.

Sandoz is responsible for funding all of the legal expenses incurred under the 2006 Sandoz Collaboration Agreement; 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, 2015, the Company recorded $43.4 million in product revenues from Sandoz' sales of GLATOPA, reflecting $52.5 million in profit share net of a deduction of $9.1 million for reimbursement to Sandoz of the Company's 50% share of pre-launch GLATOPA-related legal expenses. These expenses consist primarily of the costs incurred by Sandoz in connection with the patent infringement suit brought in 2008 by Teva Pharmaceuticals Industries Ltd. and related parties. See Note 14 *"Commitments and Contingencies"* for information on the suit. In the year ended December 31, 2015, the Company earned a $10.0 million regulatory milestone payment upon GLATOPA receiving sole FDA approval and an additional $10.0 million milestone payment upon the first commercial sale. The Company is eligible to receive in the aggregate up to $120.0 million in additional milestone payments upon the achievement of certain commercial and sales-based milestones for GLATOPA and M356 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 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 M356, if clinical trials are required for regulatory approval of M356.

Under the stock purchase agreement, the Company sold approximately 4.7 million shares of its common stock to Novartis for an aggregate purchase price of $75.0 million, representing a premium of $13.6 million based on the closing price of the Company's common stock on the NASDAQ Global Market on the on the date of purchase. The premium was recognized as revenue on a straight-line basis over the estimated development period. See "Amortization of upfront payments" in the tables above for research and development revenue earned by the Company relating to this paid premium. The equity premium has been earned as of December 31, 2014.

The Company recognizes research and development revenue from FTE services and research and development revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs is 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 development and related services, except with respect to any amounts due Sandoz for shared development costs, which are recorded on a net basis. See "Research and development services and external costs" in the tables above for research and development revenue earned by the Company from FTE services and external development costs under the 2006 Sandoz Collaboration Agreement.

Baxalta Collaboration Agreement

The Company and Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, referred to as "Baxter") entered into a global collaboration and license agreement effective February 2012, or the Baxter Collaboration Agreement, to develop and commercialize biosimilars, including M923. In connection with Baxter's internal corporate restructuring in July 2015, Baxter assigned all of its rights and obligations under the Baxter Collaboration Agreement

to Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated (collectively, "Baxalta"). In light of the assignment, all references to "Baxter" and the "Baxter Collaboration Agreement" have been replaced with references to "Baxalta" and the "Baxalta Collaboration Agreement," respectively.

Under the Baxalta Collaboration Agreement, 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, 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: M511, the Company's biosimilar AVASTIN® (bevacizumab) candidate. In December 2013, Baxalta terminated its option to license M511 under the Baxalta Collaboration Agreement following an internal portfolio review. In February 2015, Baxalta's right to select additional programs expired without being exercised. Also in February 2015, Baxalta terminated in part the Baxalta Collaboration Agreement as it relates specifically to M834 and all worldwide development and commercialization rights for M834 reverted to the Company. The Baxalta Collaboration Agreement remains in effect and unchanged with respect to M923.

Under the Baxalta Collaboration Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize M923 for all therapeutic indications. The Company has agreed to provide development and related services on a commercially reasonable basis through the filing of an Investigational New Drug application, or IND, or equivalent application in the European Union for M923. Development and related services include high-resolution analytics, characterization, and product and process development. Baxalta is responsible for clinical development, manufacturing and commercialization activities and will exclusively distribute and market M923. The Company has 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, will be borne by the parties in varying proportions, depending on the type of expense and the stage of development. The Company is reimbursed at a contractual FTE rate for any full-time equivalent employee expenses and external development costs for reimbursable activities related to M923.

Baxalta has a right of first negotiation with respect to collaborating with the Company on the development of any biosimilar product candidate that could compete with M923 based on the same mechanism of action. This right is effective until December 2017, subject to certain restrictions as outlined in the Baxalta Collaboration Agreement. Under the terms of the Baxter Agreement, the Company received an initial cash payment of $33.0 million, a $7.0 million license payment for achieving pre-defined "minimum development criteria" for M834, and $12.0 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 is eligible to receive from Baxalta, in aggregate, up to $50.0 million in regulatory milestone payments for M923, on a sliding scale, where, based on the product's regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval.

In addition, if M923 is successfully developed and launched, Baxalta will be required to pay to 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 be slightly more than double the base royalty.

The term of the collaboration shall continue throughout the development and commercialization of M923 on a country-by-country basis until there is no remaining payment obligation with respect to the product in the relevant territory, unless earlier terminated by either party pursuant to the terms of the Baxalta Collaboration Agreement.

The Baxalta Collaboration Agreement may be terminated by:

- either party for breach by or bankruptcy of the other party;
- Baxalta for its convenience; or
- the Company in the event Baxalta does not exercise commercially reasonable efforts to commercialize M923 in the United States or other specified countries, provided that the Company also has certain rights to directly commercialize M923, as opposed to terminating the Baxalta Collaboration Agreement, in event of such a breach by Baxalta.

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) the development and product licenses to M923, M834 and the four additional reference products, (ii) the research and development services related to M923, M834 and the four additional reference products and (iii) the Company's participation in a joint steering committee. The Company has determined that each of the license deliverables do not have stand-alone value apart from the related research and development services deliverables as there are no other vendors selling similar, competing products on a stand-alone basis, Baxalta does not have the contractual right to resell the license, and 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 separate units of accounting exist for each of the six licenses together with the related research and development services, as well as the joint steering committee with respect to this arrangement. The estimated selling prices for these units of accounting were 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, the arrangement consideration of $61.0 million, which included the $33.0 million upfront payment and aggregate option payments for the four additional reference 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 reference products 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 lapsing 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 $61.0 million to $40.0 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 $40.0 million to the remaining deliverables under the agreement using the original best estimate of selling price. The remaining deliverables are 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. Of the $40.0 million, $39.6 million was allocated to the M923 product

license together with the related research and development services and $0.4 million was allocated to the joint steering committee unit of accounting. The Company recognized the resulting change in revenue as a result of the decrease in deliverables and expected consideration on a prospective basis beginning in the first quarter of 2015. The Company records this revenue on a straight-line basis over the applicable performance period, 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 M923 and for the joint steering committee is approximately six years. As of December 31, 2015, $22.0 million of revenue was deferred under this agreement, of which $9.8 million was included in current liabilities and $12.2 million was included in non-current liabilities in the consolidated balance sheet.

The Company recognizes research and development revenue from FTE services and research and development revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs is 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 development and related services. Beginning in 2013, the Company commenced billing to Baxalta FTE services and external development costs for reimbursable activities related to M923. See tables above for research and development revenue earned by the Company under the Baxalta Collaboration Agreement.

The Company has concluded that the M923 technical development milestones and the IND milestones pursuant to the Baxalta Collaboration Agreement are substantive. The Company evaluated factors such as the scientific and regulatory risks that must be overcome to achieve these milestones, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Revenues from the non-refundable, technical development and IND milestones were recognized upon successful accomplishment of the milestones as research and development revenue.

The regulatory milestones, along with any associated royalty or profit sharing payments, will be considered contingent fees that will be recorded as earned in future periods.

10. Preferred, Common and Treasury Stock

Preferred Stock

The Company is authorized to issue 5.0 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, 2015 and 2014, 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. Restricted stock awards generally vest ratably over four years. Incentive and non-statutory stock options generally expire ten years after the date of grant. Restricted stock awards have been granted only to employees of the Company.

The total number of shares reserved for issuance under the 2013 Plan before giving effect to the amendment and restatement described below equaled the sum of: (a) 5,100,000, (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) 1.35 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).

On March 11, 2015, the board of directors approved an amendment and restatement of the 2013 Plan subject to and effective upon stockholder approval. At the Company's 2015 Annual Meeting of Stockholders, held on June 9, 2015 (the "Annual Meeting"), stockholders approved the amendment and restatement of the 2013 Plan. The amendment and restatement increased (1) the number of shares of common stock available for issuance under the 2013 Plan by 2,550,000 shares and (2) the fungible ratio under the 2013 Plan such that any shares subject to awards granted under the 2013 Plan on or after June 9, 2015 or that, on or after such date, become available for grant under the 2013 Plan upon forfeiture, expiration or cash settlement of awards granted under the Plan on or after June 9, 2015 or awards granted under the Prior Plans, in each case, other than awards that are options or stock appreciation rights, are counted against or, as applicable, added to the aggregate number of shares available for issuance under the 2013 Plan as 1.67 shares for every one share granted.

The following table is a roll-forward of shares available for issuance under the 2013 Plan for the period beginning June 11, 2013 through the year ended December 31, 2015 (in thousands):

	Shares Available for Issuance
Shares reserved for issuance at June 11, 2013	3,300
Add:	
Stockholder-approved increase in share pool in 2014	1,800
Stockholder-approved increase in share pool in 2015	2,550
Stock options and restricted stock awards forfeited or expired under prior plans	630
Stock options and awards forfeited under 2013 Plan	278
Less:	
Stock options and awards granted under 2013 Plan	(4,009)
Shares reserved for issuance at December 31, 2015	4,549

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 following table summarizes share-based compensation expense recorded in the years ended December 31, 2015, 2014 and 2013 (in millions):

	2015	2014	2013
Outstanding employee and non-employee stock option grants	$ 10.5	$ 9.7	$ 8.1
Outstanding restricted stock awards	0.5	3.5	4.3
Employee stock purchase plan	0.4	0.4	0.4
Total compensation cost	$ 11.4	$ 13.6	$ 12.8

During the year ended December 31, 2015, the Company granted 1,635,796 stock options, of which 1,190,146 were granted in connection with annual merit awards, 124,250 were granted to the Company's board of directors, and 321,400 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		
	2015	2014	2013	2015	2014	2013
Expected volatility	59%	66%	63%	59%	63%	64%
Expected dividends	—	—	—	—	—	—
Expected life (years)	6.1	6.1	6.0	0.5	0.5	0.5
Risk-free interest rate	1.9%	2.2%	1.5%	0.1%	0.1%	0.1%

The following table presents stock option activity of the 2013 Plan and Prior Plans for the year ended December 31, 2015:

	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, 2014	7,110	$ 14.43		
Granted	1,635	14.61		
Exercised	(1,737)	13.57		
Forfeited	(157)	14.71		
Expired	(240)	18.52		
Outstanding at December 31, 2015	6,611	$ 14.54	6.45	$ 9,041
Exercisable at December 31, 2015	4,211	$ 14.09	5.21	$ 6,507
Vested or expected to vest at December 31, 2015	6,362	$ 14.52	6.35	$ 8,777

The weighted average grant date fair value of option awards granted during 2015, 2014 and 2013 was $8.11, $10.51 and $7.62 per option, respectively. The total intrinsic value of options exercised during 2015, 2014 and 2013 was $11.4 million, $1.3 million and $2.7 million, respectively. At December 31, 2015, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $16.3 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.4 years. The total fair value of options vested during 2015, 2014 and 2013 was $9.9 million, $10.1 million and $8.3 million, respectively.

Cash received from option exercises for 2015, 2014 and 2013 was $23.6 million, $2.2 million and $4.2 million, respectively.

Restricted Stock Awards

The Company has also made awards of time-based and performance-based restricted common stock to employees and officers. During the year ended December 31, 2015, the Company awarded 255,087 shares of time-based restricted common stock primarily to its 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. 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 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 GLATOPA on April 16, 2015. The Company is recognizing 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 expected to vest will be expensed over the period beginning on March 11, 2015 and ending on April 16, 2016, the one year anniversary of FDA approval. Accordingly, approximately $8.1 million of stock compensation cost was recognized in the period beginning March 11, 2015 and ending December 31, 2015. As of December 31, 2015, the total remaining unrecognized compensation cost related to the nonvested portion of the modified awards amounted to $1.2 million, which is expected to be recognized over the weighted average remaining requisite service period of 0.3 years.

As of December 31, 2015, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $6.8 million, which is expected to be recognized over the weighted average remaining requisite service period of 1.7 years.

A summary of the status of nonvested shares of restricted stock as of December 31, 2015 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, 2015	1,174	$ 15.15
Granted	255	13.19
Vested	(517)	15.15
Forfeited	(151)	14.55
Nonvested at December 31, 2015	761	$ 14.61

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of December 31, 2015 are summarized below (in thousands):

Vesting Schedule	Nonvested Shares
Time-based	449
Performance-based	312
Nonvested at December 31, 2015	761

The total fair value of shares of restricted stock vested during 2015, 2014 and 2013 was $7.9 million, $2.0 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 109,506 shares of common stock to employees under the ESPP during the year ended December 31, 2015. As of December 31, 2015, 637,474 shares of common stock have been issued to the Company's employees under the ESPP, and 387,178 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, 2015, subscriptions were outstanding for an estimated 32,533 shares at a fair value of approximately $6.49 per share. The weighted average grant date fair value of the offerings during 2015, 2014 and 2013 was $4.05, $4.51 and $4.73 per share, respectively. Cash received from the ESPP for 2015, 2014 and 2013 was approximately $1.0 million, $1.1 million and $0.9 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, 311,459 performance-based restricted common stock awards which vest on the one year anniversary of the U.S. Food and Drug Administration, or FDA, approval for GLATOPA in the United States (April 16, 2016) were excluded from diluted shares outstanding as the vesting condition for the amended awards, discussed further in Note 11 " *Share-Based Payments* ," had not been met as of December 31, 2015.

The following table presents anti-dilutive shares for the years ended December 31, 2015, 2014 and 2013 (in thousands):

	2015	2014	2013
Weighted-average anti-dilutive shares related to:			
Outstanding stock options	4,148	5,941	4,492
Restricted stock awards	519	847	929

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, 2015 and 2014 are as follows, in thousands:

	2015	2014
Deferred tax assets:		
Federal and state net operating losses	$ 115,583	$ 80,549
Research credits	23,353	18,773
Deferred compensation	10,031	14,391
Deferred revenue	8,635	12,176
Accrued expenses	3,023	2,851
Intangibles	3,300	3,441
Depreciation	686	838
Unrealized loss on marketable securities	1	6
Total deferred tax assets	164,612	133,025
Valuation allowance	(164,612)	(133,025)
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, 2015, 2014 and 2013 is as follows (in thousands):

	2015	2014	2013
Benefit at federal statutory tax rate	$ (28,323)	$ (33,521)	$ (36,856)
State taxes, net of federal benefit	(4,398)	(5,206)	(5,724)
Share-based compensation	3,634	2,411	2,106
Tax credits	(2,652)	(5,529)	(2,404)
Other	42	23	15
Change in valuation allowance	31,697	41,822	42,863
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 $31.6 million for the year ended December 31, 2015 due primarily to the current period net loss.

At December 31, 2015, the Company had federal and state net operating loss carryforwards of $313.6 million and $286.0 million, respectively, available to reduce future taxable income that will expire at various dates through 2035. Of this amount, approximately $15.6 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, 2015, the Company had federal and state

research and development and other credit carryforwards, including the orphan drug credit, of $21.6 million and $10.0 million, respectively, available to reduce future tax liabilities that expire at various dates through 2035. 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, 2015 and 2014 is as follows (in thousands):

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

As of December 31, 2015 and 2014, the Company had $5.1 million and $4.1 million of gross unrecognized tax benefits, respectively, of which $4.9 million and $3.9 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 2012, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2012.

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 must 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 does not maintain its job creation commitments. As the Company attained its job creation commitment in 2012 and has maintained it since then, it recognized one-fifth of the $1.1 million job creation tax award, or $0.2 million, as other income in each year beginning 2012 to 2015. The unearned portion of the award is included in other liabilities in the consolidated balance sheet. The Company will continue to recognize an equal portion of the award as other income over the five year period it must maintain its job creation commitments.

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 $16.4 million, $16.3 million and $12.8 million for the years ended December 31, 2015, 2014 and 2013, 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.

In December 2011, the Company entered into an agreement to lease 68,575 square feet of office and laboratory space located on the first and second floors at 320 Bent Street, Cambridge, Massachusetts, for a term of approximately 18 months, or the First Bent Street Sublease. The Company gained access to the subleased space in December 2011 and, consequently, the Company commenced expensing the applicable rent on a straight-line basis beginning in December 2011. Annual rental payments due under the First Bent Street Sublease were approximately $2.3 million.

On February 5, 2013, the Company and BMR-Rogers Street LLC, or BMR, entered into a lease agreement, or the Second 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 Second Bent Street 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.

Under the Second Bent Street Lease, the Company has two consecutive options to extend the term of the Second Bent Street 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 Second Bent Street 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.

On October 27, 2015, the Company exercised its option to extend the term of the Second Bent Street Lease for one year to August 31, 2017.

On December 30, 2015, the Company and BMR entered into an amendment ("the Amendment") to Second Bent Street Lease agreement. 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.

Under the Amendment, provided that the Company has not assigned the lease or subleased more than 45 percent of the Premises, the Company will have one option to extend the term of the lease beyond the expiration date of the lease by five years at the then-current fair market value. Monthly base rent during the term of the option period may be increased annually in accordance with then-current fair market value.

The Amendment also provides the Company with a right of first offer as to all rentable premises in the building located at 320 Bent Street that next become available and for which BMR is seeking a tenant, subject to certain conditions. In addition, if the tenant of the building located at 301 Binney Street, Cambridge Massachusetts (the "Binney Building") has entered into an agreement with BMR to terminate its lease of the fifth floor of such building prior to the expiration of its lease term, the Company will have a one-time right of first offer with respect to all rentable premises on the fifth floor of the Binney Building that become available pursuant to the termination agreement. The Amendment deletes the provision of the Lease granting the Company a right of first refusal for certain rentable premises in the building located at 675 West Kendall Street in Cambridge, Massachusetts ("675 Kendall Building").

If the Company enters into a lease with BMR or an affiliate of BMR for premises totaling more than 175,000 square feet of rentable area in the Binney Building or another building owned by an affiliate of BMR, the Company will be entitled to terminate the lease with respect to the entire Premises. The Amendment deletes the provision in the lease providing for early termination of the lease upon the execution of a lease of certain premises in the 675 Kendall Building.

Total operating lease commitments as of December 31, 2015 are as follows (in thousands):

	Operating Leases
2016	$ 9,254
2017	11,023
2018	9,193
2019	7,807
2020	8,035
2021 and beyond	54,278
Total future minimum lease payments	$ 99,590

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.

M356-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 suit against the Company and Sandoz in the United States Federal District Court in the District of Delaware in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for M356. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and seeks declaratory and injunctive relief prohibiting the launch of the Company's product until the last to

expire of these patents. In April 2015, Teva and Yeda filed an additional suit against the Company and Sandoz in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in March 2015 and expires in 2030. In May 2015, this suit was consolidated with the initial suit filed in September 2014. In November 2015, Teva and Yeda filed a suit against the Company and Sandoz in the United States District Court for the District of Delaware alleging infringement related to a fourth Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in October 2015 and expires in 2030. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of M356 until the expiration of this patent. In December 2015, this suit was consolidated with the initial suit filed in September 2014. The Company and Sandoz have asserted various defenses and filed counterclaims for declaratory judgments of non-infringement, invalidity and unenforceability of the COPAXONE 40 mg/mL patents. A pre-trial claim construction hearing was held in February 2016 and the trial is scheduled to begin in September 2016.

Enoxaparin Sodium Injection-related Litigation

On September 21, 2011, the Company and Sandoz sued Amphastar, International Medical Systems, Ltd., a wholly owned subsidiary of Amphastar and, together with Amphastar ("Amphastar") and Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.), or 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 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 and in June 2013 the Supreme Court denied the petition.

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. 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. Amphastar has filed motions to increase the amount of the security bond, which the Company and Sandoz have opposed.

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

and fees. In December 2015, the Company and Sandoz filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting the court to reverse and review the District Court's grant of transfer. While the outcome of litigation is inherently uncertain, the Company believes this suit is without merit, and the Company intends to vigorously defend itself in this litigation.

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital ("NGH") filed a class action suit against the Company and Sandoz in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic enoxaparin sodium injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz sought to prevent Amphastar from selling generic enoxaparin sodium injection and thereby exclude competition for generic enoxaparin sodium injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, the Company and Sandoz filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. These motions are pending before the 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 $0.9 million, $0.9 million and $0.8 million of such match expense in the years ended December 31, 2015, 2014 and 2013, 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. The Company intends to use these proceeds for general corporate purposes, including working capital.

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 intends to use the net proceeds from this facility to advance its development pipeline and for general corporate purposes, including working capital. 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.

Between October 2014 and April 2015, the Company sold approximately 5.4 million shares of common stock under the 2014 ATM Agreement, raising aggregate net proceeds of approximately $73.5 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.

17. Selected Quarterly Financial Data (Unaudited)

	Quarter Ended			
(in thousands, except per share data)	March 31	June 30	September 30	December 31
2015				
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
2014				
Product revenue	$ 4,812	$ 5,690	$ 4,714	$ 4,747
Research and development revenue	$ 5,973	$ 5,260	$ 4,622	$ 16,432
Total collaboration revenue	$ 10,785	$ 10,950	$ 9,336	$ 21,179
Net loss	$ (27,362)	$ (26,156)	$ (29,101)	$ (15,981)
Comprehensive loss	$ (27,378)	$ (26,119)	$ (29,127)	$ (16,017)
Basic and diluted net loss per common share	$ (0.53)	$ (0.51)	$ (0.56)	$ (0.31)
Shares used in computing basic and diluted net loss per common share	51,356	51,466	51,545	52,255

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

On January 8, 2016, the Company and Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., or 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 world-wide basis, to develop, manufacture and commercialize six of the Company's biosimilar candidates, including M834.

Under the terms of the Mylan Collaboration Agreement, Mylan has agreed to pay the Company a non-refundable upfront payment of $45 million. In addition, the Company and Mylan will 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 the Company, 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, 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 has 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 has 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, or JSC, for such product candidates if the Company exercises its co-commercialization option described below. The Company and Mylan have established a JSC consisting of an equal number of members from the Company and Mylan, to oversee and manage the development, manufacture and commercialization of product candidates under the collaboration. Unless otherwise determined by the JSC, it is anticipated that, in collaboration with the other party, (a) the Company will be primarily responsible for nonclinical development activities and initial clinical development activities for product candidates; 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 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 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 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.

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, 2015. 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, 2015, 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, 2015, 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, 2015, 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, 2015, 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, 2015, 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, 2015 and 2014, and the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015 of Momenta Pharmaceuticals, Inc. and our report dated February 26, 2016 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 26, 2016

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended December 31, 2015 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 2016 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We make available our code of business conduct and ethics free of charge through our website which is located at *www.momentapharma.com* . We intend to disclose any amendment to, or waiver from, our code of business conduct and ethics that is required to be publicly disclosed pursuant to rules of the Securities and Exchange Commission and the NASDAQ Global 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 2016 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 2016 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 2016 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 2016 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 2016 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:

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.

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 26, 2016

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

Signature	Title	Date
/s/ CRAIG A. WHEELER Craig A. Wheeler	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2016
/s/ RICHARD P. SHEA Richard P. Shea	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2016
/s/ JAMES SULAT James Sulat	Chairman of the Board of Directors	February 26, 2016
/s/ GEORGES GEMAYEL Georges Gemayel	Director	February 26, 2016
/s/ BRUCE DOWNEY Bruce Downey	Director	February 26, 2016
/s/ MARSHA H. FANUCCI Marsha H. Fanucci	Director	February 26, 2016
/s/ THOMAS KOESTLER, Ph.D. Thomas Koestler, Ph.D.	Director	February 26, 2016
/s/ BENNETT M. SHAPIRO, M.D. Bennett M. Shapiro, M.D.,	Director	February 26, 2016
/s/ ELIZABETH STONER, M.D. Elizabeth Stoner, M.D.,	Director	February 26, 2016

EXHIBIT INDEX

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to Exhibit No.	Filing Date with SEC	SEC File Number
	Articles of Incorporation and By-Laws				
3.1	Third Amended and Restated Certificate of Incorporation	S-3	3.1	4/30/2013	333-188227
3.2	Certificate of Designations of Series A Junior Participating Preferred Stock of the Registrant	8-K	3.1	11/8/2005	000-50797
3.4	Third Amended and Restated By-Laws	8-K	3.1	12/15/2014	000-50797
	Instruments Defining the Rights of Security Holders				
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	4.1	6/15/2004	333-113522
4.2	Investor Rights Agreement, dated as of July 25, 2006, by and between Novartis Pharma AG and the Registrant	10-Q	10.2	11/8/2006	000-50797
	Material Contracts—License Agreements				
10.1†	Collaboration and License Agreement, dated November 1, 2003, by and among Biochemie West Indies, N.V., Geneva Pharmaceuticals, Inc. and the Registrant	S-1/A	10.4	5/11/2004	333-113522
10.1.1†	Amendment to Collaboration and License Agreement, dated April 1, 2015, by and between Sandoz AG (f/k/a Biochemie West Indies, N.V.), Sandoz Inc. (f/k/a Geneva Pharmaceuticals, Inc.), and the Registrant	8-K	10.1	6/19/2015	000-50797
10.2	Letter Agreement dated January 29, 2007 between Sandoz AG and the Registrant	10-K	10.16	3/15/2007	000-50797
10.3	Letter Agreement dated February 1, 2007 between Sandoz AG and the Registrant	10-Q	10.2	5/10/2007	000-50797
10.4†	Collaboration and License Agreement, dated June 13, 2007, by and among Sandoz AG and the Registrant	10-Q	10.1	8/9/2007	000-50797
10.4.1	Amendment No. 1, dated April 25, 2008, to the Collaboration and License Agreement, dated June 13, 2007, by and among Sandoz AG and the Registrant	10-Q	10.1	5/9/2008	000-50797
10.4.2†	Amendment No. 2, dated December 14, 2009, to the Collaboration and License Agreement, dated June 13, 2007, by and among Sandoz AG and the Registrant	10-K	10.18	3/12/2010	000-50797
10.4.3	Amendment No. 3, dated April 1, 2011, to the Collaboration and License Agreement dated June 13, 2007 by and among Sandoz AG and the Registrant.	10-Q	10.1	8/5/2011	000-50797
10.5	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

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.6†	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
	Material Contracts—Management Contracts and Compensation Plans				
10.7#	Amended and Restated 2002 Stock Incentive Plan	10-K	10.17	3/15/2007	000-50797
10.8#	2004 Stock Incentive Plan, as amended	10-K	10.18	3/15/2007	000-50797
10.9#	Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.1	8/16/2004	000-50797
10.10#	Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.2	8/16/2004	000-50797
10.11#	Form of Restricted Stock Agreement Under 2004 Stock Incentive Plan	8-K	10.2	2/28/2008	000-50797
10.12#	2004 Employee Stock Purchase Plan (as amended and restated)	8-K	10.2	6/17/2014	000-50797
*10.13#	Non-Employee Director Compensation Summary				
10.14#	Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.14.1#	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
10.15#	Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.8	11/8/2006	000-50797
10.16#	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 December 15, 2006, between John E. Bishop and the Registrant	10-K	10.56	3/15/2007	000-50797
10.19#	Restricted Stock Agreement, dated December 14, 2007, between John E. Bishop and the Registrant	10-K	10.35	3/10/2008	000-50797
10.20#	Restricted Stock Agreement, dated August 15, 2007, between Richard P. Shea and the Registrant	10-Q	10.1	11/08/2007	000-50797
10.21#	Form of Employment Agreement for executive officers	10-Q	10.3	5/9/2008	000-50797
10.22#	Second Amended and Restated Employment Agreement, dated April 28, 2008, by the Registrant and Ganesh Venkataraman	10-Q	10.4	5/9/2008	000-50797

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.23#	Form of Amendment to Employment Agreement, dated May 28, 2008, by the Registrant and each of John E. Bishop and James Roach	10-Q	10.1	8/5/2008	000-50797
10.24#	Form of Amendment to the Employment Agreement for executive officers dated December 15, 2010	10-K	10.39	3/10/2011	000-50797
10.25#	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
10.26#	Form of Restricted Stock Agreement	8-K	10.1	4/1/2011	000-50797
10.27#	Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan (as amended and restated)	8-K	10.1	6/17/2014	000-50797
10.28#	Form of Stock Option Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan	8-K	10.1	6/13/2013	000-50797
10.29#	Form of Restricted Stock Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan	8-K	10.2	6/13/2013	000-50797
	Material Contracts—Leases				
10.30†	Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.9	11/12/2004	000-50797
10.30.1	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
10.30.2	Second Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of November 21, 2005, between Vertex Pharmaceuticals Incorporated and the Registrant	10-K	10.47	3/16/2006	000-50797
10.30.3	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
10.30.4	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
10.30.5	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

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to Exhibit No.	Filing Date with SEC	SEC File Number
10.31	Sublease Agreement, dated February 5, 2013, by and between BMR-Rogers Street LLC and the Registrant	10-Q	10.1	5/10/2013	000-50797
10.31.1	First Amendment dated March 21, 2013 to the Sublease Agreement dated February 5, 2013 by and between BMR-Rogers Street LLC and the Registrant	10-Q	10.2	5/10/2013	000-50797
10.31.2	Second Amendment to Sublease Agreement, dated May 24, 2013, by and between BMR-Rogers Street LLC and the Registrant	10-Q	10.4	8/6/2013	000-50797
10.31.3	Third Amendment to Sublease Agreement, dated December 30, 2015, by and between BMR-Rogers Street LLC and the Registrant	8-K	10.1	1/5/2016	000-50797
	Material Contracts—Stock Purchase Agreement				
10.32	Stock Purchase Agreement, dated July 25, 2006, by and between Novartis Pharma AG and the Registrant	10-Q	10.1	11/8/2006	000-50797
	Material Contracts—Asset Purchase Agreement				
10.33	Asset Purchase Agreement dated as of April 20, 2007 by and among Parivid, LLC, S. Raguram and the Registrant	10-Q	10.3	5/10/2007	000-50797
10.33.1	Amendment No. 1 to the April 20, 2007 Asset Purchase Agreement between Parivid LLC, S. Raguram and the Registrant dated August 4, 2009.	10-Q	10.2	8/6/2009	000-50797
10.33.2	Amendment No. 2 to the April 20, 2007 Asset Purchase Agreement between Parivid LLC, S. Raguram and the Registrant dated July 18, 2011	10-Q	10.2	8/5/2011	000-50797
	Material Contracts—At-the-Market Facility				
10.34	At-The-Market Equity Offering Sales Agreement, dated as of May 6, 2014, by and between the Registrant and Stifel, Nicolaus & Company, Incorporated	8-K	10.1	5/06/2014	000-50797
10.35	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
	Additional Exhibits				
*21	List of Subsidiaries				
*23.1	Consent of Independent Registered Public Accounting Firm				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
**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 Calculation Linkbase Document.				
*101.LAB	XBRL Taxonomy Label Linkbase Document.				
*101.PRE	XBRL Taxonomy Presentation Linkbase Document.				
*101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
*101.REF	XBRL Taxonomy Reference Linkbase Document.				

* Filed herewith.

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

Management contract or compensatory plan or arrangement.

** Furnished herewith

The following financial information from Momenta Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the period ended December 31, 2015, filed with the SEC on February 26, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Comprehensive Loss for the years ended December 31, 2015, 2014 and 2013, (ii) the Consolidated Balance Sheets as of December 31, 2015 and 2014, (iii) the Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013, (iv) the Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013 and (v) Notes to Consolidated Financial Statements.

Exhibit 10.13

Non-Employee Director Compensation Summary

The compensation program for non-employee directors of Momenta Pharmaceuticals, Inc. (the "Company") is summarized as follows:

Grant of Options Upon Appointment

Each new non-employee director receives an option to purchase 30,000 shares of the Company's common stock upon election or appointment to the Company's Board of Directors (the "Board"), with 1/3 of such option vesting on the first anniversary of the date of election or appointment and an additional 8 1/3% vesting at the end of every three-month period thereafter, subject to the director's continued service to the Company. Each such 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.

Grant of Additional Stock Options

Each non-employee director who served as a director in the previous year receives an option to purchase 17,750 shares of the Company's common stock on the date of each annual meeting of the Company's stockholders, such option vests in full on the first anniversary of the grant date, subject to the director's continued service to the Company. Each such 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.

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:

Position	Fees
Annual Retainer	$40,000
Non-Employee Chairman of the Board	$30,000
Audit Committee Chair	$20,000
Audit Committee Members (other than the Chair)	$10,000
Compensation Committee Chair	$15,000
Compensation Committee Members (other than the Chair)	$7,500
Nominating and Corporate Governance Committee Chair	$12,000
Nominating and Corporate Governance Committee Members (other than the Chair)	$6,000
Science Committee Chair	$10,000
Science Committee Members	$7,500
Additional Payments to Science Committee Chair and Members	$3,000 for each all day session attended (up to a maximum of $15,000 per year) that is in addition to the standard quarterly meetings of the Scientific Committee

All retainer amounts 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 Board meetings.

EXHIBIT 21

SUBSIDIARIES OF MOMENTA PHARMACEUTICALS, INC.

Name of Subsidiary	Jurisdiction of Organization
Momenta Pharmaceuticals Securities Corporation	Massachusetts

QuickLinks

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 333-188227 and 333-161414 and Form S-8 Nos. 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. and of our reports dated February 26, 2016, 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, 2015.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 26, 2016

QuickLinks

Exhibit 31.1

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 26, 2016

/s/ CRAIG A. WHEELER

Craig A. Wheeler
President and Chief Executive Officer

QuickLinks

Exhibit 31.2

CERTIFICATIONS

I, Richard P. Shea, 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 26, 2016

/s/ RICHARD P. SHEA

Richard P. Shea
Senior Vice President and Chief Financial Officer

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Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2015 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 Richard P. Shea, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

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

Dated: February 26, 2016

/s/ CRAIG A. WHEELER

Craig A. Wheeler
President and Chief Executive Officer

Dated: February 26, 2016

/s/ RICHARD P. SHEA

Richard P. Shea
Senior Vice President and Chief Financial Officer

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