MOMENTA PHARMACEUTICALS INC

FORM 10-K
(Annual Report)

Filed 02/27/15 for the Period Ending 12/31/14

Address	675 WEST KENDALL STREET CAMBRIDGE, MA 02142
Telephone	617 491-9700
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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, 2014

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, 2014, based on $12.08 per share, the last reported sale price of Common Stock on the Nasdaq Global Market on that date, was $623,539,919.

As of February 13, 2015, the registrant had 54,972,790 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 2015 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, efforts to partner our un-partnered programs, including without limitation M834, the timing of clinical trials and the significance and meaning of results of clinical trials, our ongoing litigation with Teva over M356, 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.

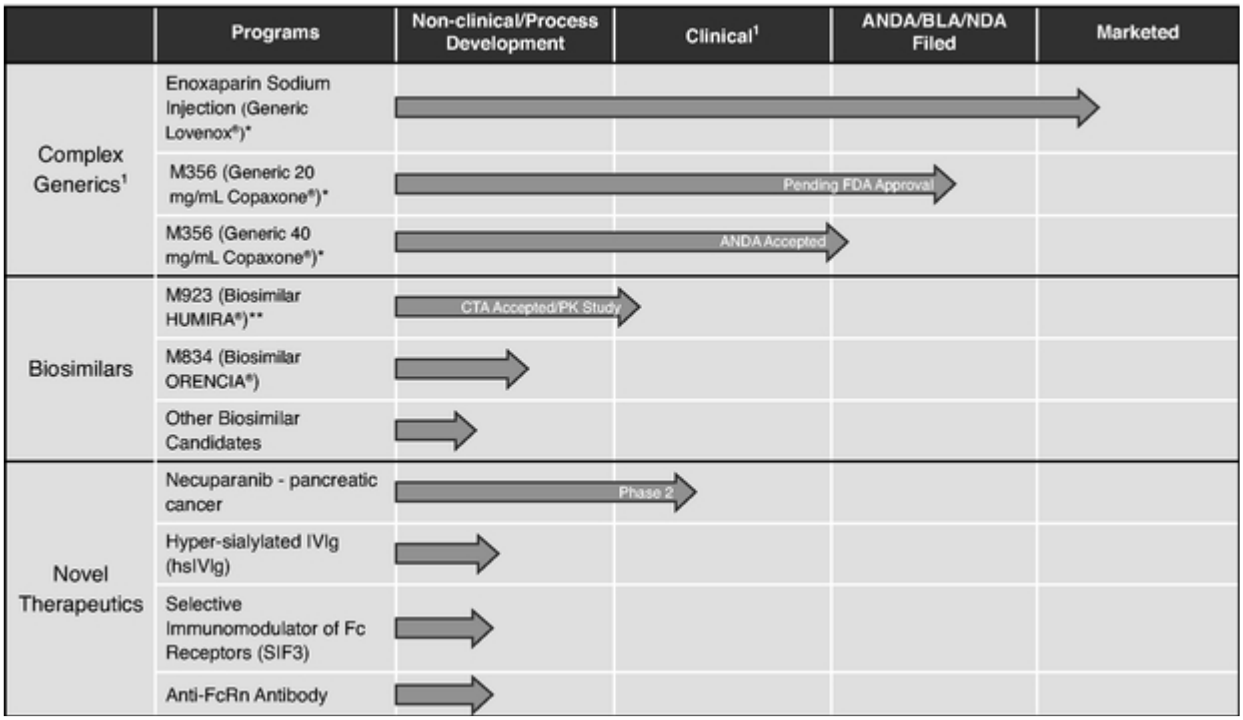
We were originally founded to develop novel therapeutics by applying our innovative sugar sequencing technology. We expanded our focus, applying our analytic technology and expertise to develop complex generics and biosimilars, seeking to take advantage of the abbreviated development and regulatory pathways available to these types of products in an effort to minimize time-to-market and secure near-term product revenues. Our first product, a generic version of Lovenox® (enoxaparin sodium injection), was approved by the FDA in July 2010. Our product was the only generic version of Lovenox on the market until September 2011, during which time we recognized product revenues of over $340 million.

In addition to our generic version of Lovenox, which continues to be marketed in the United States, we currently are developing a generic version of Copaxone® (glatiramer acetate); a portfolio of biosimilar candidates, including a biosimilar of HUMIRA® (adalimumab) and a biosimilar of ORENCIA® (abatacept); a novel oncology product candidate, necuparanib; and several novel product candidates targeting 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.

We believe our complex systems analysis platform gives us a competitive advantage in developing complex generics, biosimilars and novel therapeutics. Further, 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. Similarly, the process development and manufacturing expertise developed in our complex generics and biosimilars programs can be directly used to advance our novel therapeutic 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 deep 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 of our product areas is set forth below.



[1] Clinical safety/efficacy trials have not been required for these complex generic drug applications
****In collaboration with Sandoz***
*****In collaboration with Baxter***

Complex Generics

Our Approach

We seek to develop generic versions of complex drugs. Generics are chemical and therapeutic equivalents of brand name drugs that were approved by the United States Food and Drug Administration, or FDA, under New Drug Applications, or NDAs. Most 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. We target these complex brand name drugs using our complex systems analysis platform to define their detailed structures. Once the precise structures are identified, or characterized, this structural characterization of the brand name drug is used to guide the development of a precise manufacturing process to produce a generic version. To demonstrate the biological function of our generic version of a brand name drug, we utilize our complex systems analysis platform to evaluate and compare multiple orthogonal sets of biologic data from in-vitro, in-vivo and ex-vivo models.

Our Programs

Enoxaparin Sodium Injection—Generic Lovenox®

Enoxaparin Sodium Injection, our only approved product, is a generic version of Lovenox. Lovenox is a widely-prescribed low molecular weight heparin, or LMWH, used for the prevention and treatment of deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. 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 receive a percentage royalty on contractually defined net sales. The terms of our collaboration with Sandoz are further discussed below under " *Collaborations, Licenses and Asset Purchases—Sandoz* ."

Our Enoxaparin Sodium Injection was approved by the FDA in syringe form in July 2010 and in vial form in December 2011. Our product was the only generic version of Lovenox on the U.S. market from the time it was launched through September 2011, during which time we recognized product revenues of over $340 million.

The price for branded and generic enoxaparin sodium injection products in the United States has significantly declined in the last few years, due primarily to increased generic competition. We earned $19.9 million and $16.7 million in royalties on $197 million and $213 million in U.S. sales of Enoxaparin Sodium Injection by Sandoz in 2014 and 2013, respectively. For comparison, Sanofi reported $173 million (€130 million) and $248 million (€187 million) in U.S. sales of Lovenox in 2014 and 2013, respectively.

M356—Generic Copaxone® (glatiramer acetate injection) Candidate

M356 is being developed as a generic version of Copaxone. Copaxone, a complex drug consisting of a synthetic mixture of polypeptide chains, is indicated for 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.

M356 is being developed and commercialized in the United States in collaboration with Sandoz. We are responsible for certain development activities and Sandoz is responsible for commercialization of M356. Upon approval and commercialization, we will receive 50% of contractually defined profits from M356 sales. In addition, we are eligible to receive up to $140.0 million in milestone payments from Sandoz relating to M356. The terms of our collaboration with Sandoz are further discussed below under " *Collaborations, Licenses and Asset Purchases—Sandoz* ."

The application seeking approval of our once-daily 20 mg/mL M356 was filed by Sandoz with the FDA in December 2007. An application seeking approval of our three-times-weekly 40 mg/mL M356 was filed by Sandoz in August 2014. Both applications are currently under FDA review. If we are successful in our challenge of the patents related to 40 mg/mL Copaxone, and assuming customary patent litigation timelines, we believe our three-times-weekly 40 mg/mL formulation of M356 could be approved, following expiration of any 30-month stay, if applicable, as early as the first quarter 2017. 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 $3.1 billion and $3.2 billion in U.S. sales of Copaxone (combined 20 mg/mL and 40 mg/mL) in 2014 and 2013, respectively.

Biosimilars

Background

Biologics are therapeutic products that are approved by the FDA under Biologics License Applications, or BLAs. Biologics are produced using living cells, and as such they are much more complex than simple small molecule drugs. In 2010, an abbreviated regulatory pathway was created in the United States for FDA approval of biosimilars. Biosimilars are biologics that are highly similar to reference originator biologics notwithstanding minor differences in clinically inactive components and

that have no clinically meaningful differences from their respective reference originator biologics in terms of safety, purity and potency. Under the abbreviated regulatory pathway for biosimilars, the FDA has discretion over the kind and amount of evidence required to demonstrate similarity and has indicated that, in its review of biosimilar applications, it intends to consider the totality of the evidence, including a combination of analytical data, non-clinical (or animal) studies and clinical (or human) studies. The FDA has recommended that applicants take a stepwise approach in the development of their biosimilar products.

In the United States, the FDA may designate a biosimilar as interchangeable with its reference originator biologic if it is demonstrated that the biosimilar is expected to produce the same clinical result as the reference originator biologic in any given patient and, if it is a product to be administered repeatedly in a patient, there is no safety risk or diminished efficacy in alternating between the biosimilar and the reference originator biologic. Interchangeable biosimilars may be substituted at the pharmacy for the reference originator product without the intervention of a physician. Biosimilars that receive the first designation of interchangeability also receive a period of regulatory exclusivity during which time the FDA will not designate other biosimilars of the same originator reference product to be interchangeable. Biosimilars may be approved for one or more, and possibly all, indications for which a reference originator biologic 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 originator biologic. This extrapolation of clinical data to gain approval for multiple indications is generally referred to as indication extrapolation.The biosimilar regulatory pathway is discussed in more detail below under *"Regulatory and Legal Matters—United States Government Regulation—Biosimilars."*

Market Potential

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 reference originator biologics. 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 payors of healthcare benefits. Biosimilars are expected to generally be more affordable than their reference originator biologics. 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. 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, 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 Approach

The analytics we developed to thoroughly characterize monoclonal antibodies and fusion proteins were adapted from the physicochemical analytics that were developed in our complex generics programs. Our process development and manufacturing capabilities are guided by advanced technologies from cell line selection to manufacturing in compliance with good manufacturing practices, allowing us to produce high fidelity copies of originator products. We believe we are able to select the optimum cell lines, define process parameters and manipulate the cell's outputs using effective control strategies during manufacturing. We also evaluate orthogonal sets of both structural and biologic data (biocharacterization) from in-vitro, in-vivo and ex-vivo models to compare the function of the originator product and our product. We believe our complex systems analysis platform provides us the capabilities necessary to carry out our strategy to develop high-quality biosimilars that achieve indication extrapolation and interchangeability while relying on a more selective and targeted approach to non-clinical and clinical trials.

Our Strategy

Our biosimilar strategy includes the following three key elements:

1. *Build a portfolio of well-selected programs* .

   We seek to maintain a portfolio of programs to capture the technological, manufacturing and regulatory synergies created in developing multiple biosimilar candidates. We also believe that multiple programs offer the opportunity to diversify risk and reduce dependence on revenue from any individual product. We currently have over half a dozen biosimilar programs at various stages of development. We select programs with development timelines that we believe will allow us time to develop high-quality biosimilars while still being one of the first biosimilars for each reference originator biologic.

2. *Leverage our proven analytic capabilities and expertise to realize regulatory and commercial competitive advantages* .

   We seek to develop biosimilars that have fingerprint-like similarity to their respective reference originator biologic in order to allow for more selective and targeted clinical and non-clinical trial requirements, and related time and costs, necessary to achieve biosimilarity, indication extrapolation and interchangeability. We believe our approach offers us the opportunity to provide the FDA with robust and compelling evidence that our biosimilar has highly similar structure and biologic activity as a reference originator biologic, and that we have a well-controlled manufacturing process. We believe that under its totality-of-the-evidence approach to determining biosimilarity, the FDA could rely on our analytical data to allow more selective and targeted non-clinical and clinical trials. In turn, this could significantly reduce the length and cost of clinical studies and increase the likelihood that we can achieve our goal of a designation of interchangeability for each biosimilar program.

3. *Optimally position our product candidates for success by selectively partnering with leading pharmaceutical companies.*

We seek to identify and collaborate with strategic partners who can bring best-in-class, global commercial capabilities and can help secure high quality, low cost manufacturing and distribution. We seek to leverage our capabilities and expertise to advance programs to a stage where we can derive optimal stockholder value from each of our collaborations. We have partnered our lead program, M923, with Baxter.

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, who have had an inadequate response to certain other currently available treatments. HUMIRA is marketed globally by AbbVie.

M923 is being developed and commercialized in collaboration with Baxter. We are responsible for development activities through submission of an Investigational New Drug application, or IND, to the FDA, or equivalent application in the EU, and Baxter 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 have received $12.0 million, and are eligible to receive up to an additional $50 million, in milestone payments from Baxter relating to M923. The terms of our collaboration with Baxter are further discussed below under " *Collaborations, Licenses and Asset Purchases—Baxter* ."

In December 2014, a clinical trial application, or CTA, to initiate a pharmacokinetic clinical trial for M923 was accepted by the UK Medicines and Healthcare Products Regulatory Agency. Acceptance of the CTA met two milestones under the Baxter collaboration, resulting in payment to us of an aggregate of $12.0 million in milestone payments. The trial commenced in the first quarter of 2015. Baxter is planning to submit the first regulatory application for marketing approval for M923 as early as 2017.

AbbVie reported approximately $12.5 billion in worldwide sales of HUMIRA in 2014, including approximately $6.5 billion in the United States. Total worldwide sales of HUMIRA are expected to be approximately $14.7 billion in 2018, including approximately $7.1 billion in the United States.

M834—Biosimilar ORENCIA® (abatacept) Candidate

M834 is being developed as a biosimilar of ORENCIA. ORENCIA is a 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 indicated for the treatment of patients with rheumatoid arthritis and juvenile idiopathic arthritis who have had an inadequate response to certain other currently available treatments. ORENCIA is marketed globally by Bristol-Myers Squibb and co-promoted by Ono Pharmaceutical in Japan.

M834 was previously being developed and commercialized in collaboration with Baxter. In February 2015, Baxter terminated in part our collaboration as it relates specifically to M834. Prior to termination, in October 2014, we achieved a pre-defined "minimum development criteria" milestone under the Baxter collaboration, resulting in a $7.0 million license payment to us. We retain all worldwide development and commercialization rights for M834. We plan to continue to develop M834

with a goal of being able to enter clinical development in 2016 and are currently identifying and pursuing potential opportunities to partner the program.

Bristol-Myers Squibb reported approximately $1.7 billion in worldwide sales of ORENCIA in 2014, including approximately $1.1 billion in the United States.

Other Biosimilar Programs

We are also investing in several other, earlier stage biosimilar programs that we believe will allow us to broaden our biosimilar product portfolio and technology base. Total worldwide sales of the reference originator products that we are targeting in our other biosimilar programs were approximately $9.0 billion in 2013, including approximately $5.1 billion in the United States, and are projected to be approximately $20.7 billion in 2018, including approximately $11.0 billion in the United States.

Novel Therapeutics

Our Approach

The majority of human diseases result from the interaction of a complex web of biologic systems. We believe our core analytical tools and approach 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 goal is to leverage this knowledge to identify novel targets, novel combinations of therapies, and possibly exploit the multi-targeting nature of complex mixture molecules to develop novel products that may positively modulate multiple pathways in a disease.

Our novel therapeutics programs use the characterization and process engineering capabilities and expertise developed from our complex generics and biosimilars programs—with a focus on polysaccharides and therapeutic proteins. We believe that applying our complex systems analysis platform to the discovery and development of novel medicines gives us a detailed understanding of the complex structures of our novel product candidates, their associated manufacturing processes and controls, and the targeted biologic systems. We believe it also helps us to better select targets, or sets of targets, that will yield important clinical benefit and a higher probability of success in clinical trials. As our drug candidates progress into development, by using our platform in non-clinical studies or early in the clinical trials cycle, we believe we can capture and better understand the activity of the drugs with a goal of improving success by better selection of indications and/or dosing regimens.

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® 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.

Non-Clinical 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 (Phase 1), an open-label, multiple ascending dose escalation study evaluating necuparanib in combination with Abraxane® (nab-paclitaxel) and gemcitabine; and Part B (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 Part A and reported positive top-line data. Part A involved escalating daily necuparanib doses in combination with 125 mg/m2 Abraxane and 1000 mg/m2 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-seven patients (12 patients in the first two cohorts and 25 patients in the five subsequent cohorts) received necuparanib as of data cutoff and were included in the analyses. Top-line results included:

- The most common (greater than 30% of patients) adverse events included anemia, fatigue, nausea, diarrhea, and vomiting—comparable to what has been observed for Abraxane and gemcitabine alone.

- Twelve patients were treated with the combination regimen of necuparanib, Abraxane, and gemcitabine and have completed the first 28-day cycle as of data cutoff. All 12 patients also had at least one follow up CT scan and were considered evaluable for radiographic response. Seven patients (58%) achieved a RECIST partial response (PR) and an additional 4 patients (33%) achieved stable disease (SD). Disease Control (the number of patients with Complete Response + PR + SD / total number of evaluable patients) was achieved in 11 of the 12 patients (92%).

- All 12 evaluable patients also had greater than 20% decreases, and 11 patients had greater than 50% decreases, from baseline in CA19.9 levels (a predictive biomarker for long-term outcome and treatment response in pancreatic cancer).

We believe the safety data and early signals of efficacy from Part A are very encouraging. We believe the 5 mg/kg dose has significant potential to provide significantly higher levels of activity against multiple cancer targets than traditional anticoagulant heparins have achieved. At this dose level, no significant additional toxicity to what would be expected with the underlying Abraxane / gemcitabine combination was observed. Additionally, as the necuparanib dose was increased across cohorts, no dose proportional trends in adverse events were observed. We believe this suggests the possibility of combining necuparanib with many other chemotherapy and targeted therapy standards of care in a variety of other tumor types. We plan to present more mature data from Part A in mid-2015.

In October 2014, we initiated Part B, or Phase 2, of the Phase 1/2 trial. We expect data from Phase 2 to be available as early as the end of 2016.

Other Novel Therapeutics Programs

Applying an 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, we are also developing the following three novel therapeutic programs:

- *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 opportunities to partner the further development and commercialization of this program.

- *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. Non-clinical data has demonstrated 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 late 2016.

- *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 demonstrate high potential for acute and chronic / intermittent therapies in a broad range of autoantibody driven disease. We plan to advance this program with a goal of entering clinical development in late 2016.

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

2003 Sandoz Collaboration

In 2003, we entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz Inc. to jointly develop, manufacture and commercialize Enoxaparin Sodium Injection in the United States. Sandoz N.V. later assigned its rights in the 2003 Sandoz Collaboration to Sandoz AG, an affiliate of Novartis Pharma AG. We refer to Sandoz AG and Sandoz Inc. together as Sandoz.

Under the terms of the 2003 Sandoz Collaboration, we 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, we granted Sandoz an exclusive license under our intellectual property rights to develop and commercialize injectable enoxaparin for all medical indications within the United States.

In July 2010, Sandoz began the commercial sale of Enoxaparin Sodium Injection. Under the 2003 Sandoz Collaboration, Sandoz is obligated to pay us a contractually defined profit share or a contractually defined royalty based on whether (i) there are no third-party competitors marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), (ii) a Lovenox-Equivalent Product is being marketed by Sanofi-Aventis, which distributes the brand name Lovenox, or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, or (iii) there are one or more third-party competitors which are not Sanofi-Aventis marketing a Lovenox-Equivalent Product. From July 2010 through September 2011, no third-party competitor was marketing a Lovenox-Equivalent Product; therefore, during that period, Sandoz paid us 45% of the contractual profits from the sale of Enoxaparin Sodium Injection. In September 2011, FDA approved the ANDA for the enoxaparin product of Amphastar Pharmaceuticals, Inc., or Amphastar. In October 2011, Sandoz confirmed that an authorized generic Lovenox-Equivalent Product was being marketed, which meant that Sandoz was obligated to pay us a royalty on its net sales of Enoxaparin Sodium Injection until the contractual profits from those net sales in a product year (July 1—June 30) reached a certain threshold. Upon achievement of the contractual profit threshold in December 2011, Sandoz was obligated to pay us a profit share for the remainder of the product year. In January 2012, following the grant by the Court of Appeals for the Federal Circuit, or CAFC, of a stay of the preliminary injunction previously issued by the United States District Court for the District of Massachusetts, Actavis Inc. (formerly Watson Pharmaceuticals, Inc.), or Actavis, announced that they and Amphastar launched their enoxaparin product. Consequently, in

each product year, for net sales of enoxaparin up to a pre-defined sales threshold, Sandoz is obligated to pay us a royalty on net sales at a 10% rate, and for net sales above the sales threshold, at a 12% rate.

Certain development and legal expenses may reduce the amount of profit-share, royalty and milestone payments paid to us by Sandoz. Any product liability costs and certain other expenses arising from patent litigation may also reduce the amount of profit-share, royalty and milestone payments paid to us by Sandoz, but only up to 50% of these amounts due to us from Sandoz each quarter. Our contractual share of these development and legal expenses is subject to an annual adjustment at the end of each product year, and ends with the product year ending June 2015.

The collaboration is governed by a joint steering committee and a joint project team, each consisting of an equal number of Sandoz and Momenta representatives. Most decisions must be made unanimously, with Sandoz collectively having one vote and Momenta having one vote. Sandoz has the sole authority to determine the price at which it sells Enoxaparin Sodium Injection.

We and Sandoz will indemnify each other for losses resulting from the indemnifying party's misrepresentation or breach of its obligations under the agreement. We will indemnify Sandoz if we actually misappropriate the know-how or trade secrets of a third party. Sandoz will indemnify us and our collaborators involved in the enoxaparin program for any losses resulting from any litigation by third parties, including any product liability claims with respect to Enoxaparin Sodium Injection and any other claims relating to the development and commercialization of Enoxaparin Sodium Injection. To the extent that any losses result from a third-party claim for which we are obligated to indemnify Sandoz, Sandoz will have no obligation to indemnify us. After the expiration or termination of the agreement, these indemnification obligations will continue with respect to claims that arise before or after the termination of the agreement due to activities that occurred before or during the term of the agreement.

Unless terminated earlier, the agreement will expire upon the last sale of Enoxaparin Sodium Injection by or on behalf of Sandoz in the United States. Either party may terminate the collaboration relationship for material uncured breaches or certain events of bankruptcy or insolvency by the other. Sandoz may also terminate the agreement if the product or the market lacks commercial viability, if new laws or regulations are passed or court decisions rendered that substantially diminish our legal avenues for redress, or, in multiple cases, if certain costs exceed mutually agreed upon limits. If Sandoz terminates the agreement (except due to our uncured breach) or if we terminate the agreement due to an uncured breach by Sandoz, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize injectable enoxaparin in the United States and our obligation to indemnify Sandoz will survive with respect to claims that arise due to our exclusive development or commercialization of injectable enoxaparin after the term of the agreement. In the event of a termination by Sandoz due to the incurrence of costs beyond the agreed upon limits, we must pay certain royalties to Sandoz on our net sales of injectable enoxaparin. If Sandoz terminates the agreement due to our uncured breach, Sandoz retains the exclusive right to develop and commercialize injectable enoxaparin in the United States. Sandoz's profit sharing, royalty and milestone payment obligations survive and Sandoz's obligation to indemnify us will survive with respect to claims that arise due to Sandoz's exclusive development or commercialization of injectable enoxaparin after the term of the agreement.

2006 Sandoz Collaboration

In 2006 and 2007, we entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement, with Novartis Pharma AG, and a collaboration and license agreement, as amended, or the Second Sandoz Collaboration Agreement, with Sandoz AG. Together, this series of agreements is referred to as the 2006 Sandoz Collaboration. Under the Second Sandoz

Collaboration Agreement, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356, among other products. Further, under the Second Sandoz Collaboration Agreement, we and Sandoz AG expanded the geographic markets for Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union. Under the Stock Purchase Agreement, we sold 4,708,679 shares of common stock to Novartis Pharma AG at a per share price of $15.93 (the closing price of our common stock on the NASDAQ Global Market was $13.05 on the date of purchase) for an aggregate purchase price of $75.0 million, resulting in an equity premium of $13.6 million. As of December 31, 2014, Novartis AG owns approximately 9% of our outstanding common stock.

Under the Second Sandoz Collaboration Agreement, 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 and the related product. For M356, we are generally responsible for all of the development costs in the United States. For M356 outside of the United States and for Enoxaparin Sodium Injection in the European Union, we share development costs in proportion to our profit sharing interest. All commercialization responsibilities will be borne by Sandoz AG worldwide as they are incurred for all products. We and Sandoz AG will share profits in varying proportions, depending on the product. Upon commercialization, we will earn a 50% contractual profit share on worldwide net sales of M356. Profits on net sales of M356 will be 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. We are reimbursed at cost 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 AG. Sandoz AG is responsible for funding all of the legal expenses incurred under the Second Sandoz Collaboration Agreement; however a portion of certain legal expenses, including any patent infringement damages, will be offset against the profit-sharing amounts in proportion to our profit sharing interest. We are eligible to receive up to $163.0 million in milestone payments upon the achievement of certain regulatory, commercial and sales-based milestones for M356 in the United States and Enoxaparin Sodium Injection in the European Union. The M356 milestone payments include a $10.0 million regulatory milestone payment earned upon sole approval by the FDA of M356 in the United States, a $10.0 million milestone payment upon first commercial sale of M356 in the United States and up to $120.0 million in additional milestone payments upon the achievement of certain U.S. commercial and sales-based milestones for M356. We are eligible to receive up to $23.0 million in sales-based and commercial milestones for Enoxaparin Sodium Injection in the European Union. None of these payments, once received, is refundable and there are no general rights of return in the arrangement. Sandoz AG 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 Second 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 AG is responsible for commercialization activities and will exclusively distribute and market the products.

The term of the Second 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 Second Sandoz Collaboration Agreement. The Second Sandoz Collaboration Agreement may be terminated if either party breaches the Second Sandoz

Collaboration Agreement or files for bankruptcy. In addition, either we or Sandoz AG may terminate the Second Sandoz Collaboration Agreement as it relates to the remaining products, on a product-by-product basis, if clinical trials are required.

Pursuant to the Investor Rights Agreement, we granted to Novartis Pharma AG certain registration rights and inspection rights. Specifically, Novartis Pharma AG is entitled to "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. We also granted Novartis Pharma AG inspection rights whereby, subject to certain exceptions, Novartis Pharma AG may visit and inspect our properties and records, discuss our business and financial affairs with its officers, employees and other agents, and meet, at least twice a year, with the members of our Board of Directors.

Baxter

In December 2011, we and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, collectively, Baxter, entered into a global collaboration and license agreement, or the Baxter Agreement, to develop and commercialize biosimilars. The Baxter Agreement became effective in February 2012. Under the Baxter Agreement, we and Baxter agreed to collaborate, on a world-wide basis, on the development and commercialization of two biosimilars, M923 and M834. In addition, Baxter had the right to select four additional originator biologics to target for biosimilar development under the collaboration. In July 2012, Baxter selected an additional product, a monoclonal antibody for oncology, for which we developed a biosimilar program designated as M511. In December 2013, Baxter terminated its option to license M511 under the Baxter Agreement following an internal portfolio review. In February 2015, Baxter's right to select additional programs expired without further exercise. Also, in February 2015, Baxter terminated in part the Baxter Agreement as it relates specifically to M834.

Under the Baxter 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, which include high-resolution analytics, characterization, and product and process development. Baxter 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 Baxter, 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 Baxter. Baxter has a right of first negotiation with respect to collaborating with us on the development of any product candidate competing with M923. This right is effective for a period of three years following the effectiveness of an IND exemption or waiver or regulatory authority authorization to dose humans, subject to certain restrictions as outlined in the Baxter Agreement.

Under the terms of the Baxter Agreement, we received an initial cash payment of $33.0 million, a $7.0 million license payment for achieving a pre-defined "minimum development criteria" milestone 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 Baxter's clinical trial application to initiate a pharmacokinetic clinical trial for M923. We remain eligible to receive from Baxter, 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, Baxter 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 Baxter Agreement.

The Baxter Agreement may be terminated by:

- either party for breach by or bankruptcy of the other party;
- Baxter for its convenience; or
- us in the event Baxter 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 Baxter Agreement, in event of such a breach by Baxter.

Massachusetts Institute of Technology

We have an agreement dated November 1, 2002 with the Massachusetts Institute of Technology, or M.I.T., granting us various exclusive and non-exclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to:

- methods and technologies for characterizing polysaccharides;
- certain heparins, heparinases and other enzymes; and
- carbohydrate synthesis methods.

In exchange for the licenses granted in the agreement, we pay M.I.T. license maintenance fees, royalties on certain products and services covered by the licenses and sold by us or our affiliates or sublicensees, a percentage of certain other income received by us from corporate partners and sublicensees, and certain patent prosecution and maintenance costs.

The annual license maintenance obligations, which extend through the life of the patents, are approximately $0.1 million per year. The annual payments may be applied towards royalties payable to M.I.T. for that year for product sales, sublicensing of the patent rights or joint development revenue.

We are obligated to indemnify M.I.T. and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements, unless the losses result from the indemnified parties' gross negligence or willful misconduct.

The agreement expires upon the expiration or abandonment of all patents that issue and are licensed to us by M.I.T. under such agreement. The issued patents include over 40 United States patents and foreign counterparts of some of those. Any such patent will have a term of 20 years from the filing date of the underlying application. M.I.T. may terminate the agreement immediately if we cease to carry on our business, if any nonpayment by us is not cured within 60 days of written notice or we commit a material breach that is not cured within 90 days of written notice. We may terminate the agreement for any reason upon six months' notice to M.I.T., and we can separately terminate the license under a certain subset of patent rights upon three months' notice.

We granted Sandoz a sublicense under the agreement to certain of the patents and patent applications licensed to us. If M.I.T. converts our exclusive licenses under this agreement to non-exclusive licenses due to our failure to meet diligence obligations, or if M.I.T. terminates this agreement, M.I.T. will honor the exclusive nature of the sublicense we granted to Sandoz so long as Sandoz continues to fulfill its obligations to us under the collaboration and license agreement we entered into with Sandoz. If our agreement with M.I.T. is terminated, Sandoz agrees to assume our rights and obligations to M.I.T.

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.

The contingent milestone payments are structured to include (i) potential payments of no more than $2.0 million in cash if certain milestones are achieved within two years from the date of the purchase agreement, or the initial milestones, and (ii) the issuance of up to $9.0 million of our common stock to Parivid if certain other milestones are achieved within fifteen years of the date of the purchase agreement.

In August 2009, we entered into an amendment to the purchase agreement where we agreed to extend the time period for completion of the initial milestones to June 30, 2009, specified those initial milestones that had been achieved as of June 30, 2009 and, as consideration for the completion and satisfaction of the initial milestones that were achieved, agreed to pay Parivid $0.5 million cash and to issue 91,576 shares of our common stock, at a value of $10.92 per share. In addition, in September 2009, we made a cash payment of $0.1 million to Parivid, recorded as other expense, representing the difference between the net proceeds from Parivid's sale of the shares issued in satisfaction of the initial milestones and the value of such shares as of the date of the amendment.

In July 2011, we entered into a second amendment to the purchase agreement where we agreed that a milestone payment would be made in cash rather than through the issuance of our common stock. In August 2011, we paid Parivid $6.7 million in cash, in lieu of stock, pursuant to this amendment as consideration for the completion and satisfaction of a milestone related to Enoxaparin Sodium Injection developed technology that was achieved in July 2011. We capitalized the payment as developed technology, which is included in intangible assets in our consolidated balance sheets as of December 31, 2013 and 2014. The developed technology is being amortized over the estimated useful life of the Enoxaparin Sodium Injection developed technology of approximately 10 years.

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 and making polysaccharides, peptides and glycoproteins and other heterogeneous mixtures;
- the composition of matter and use of certain heparinases, heparinase variants and other enzymes;
- methods and technologies for synthesis of polysaccharides;
- the composition of matter and use of certain novel LMWHs and other therapeutic proteins, including necuparanib;
- methods to identify, analyze and characterize glycoproteins; and
- methods of manufacture of polysaccharide, polypeptide and glycoprotein products.

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 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 facilities for manufacturing any products. Although we intend to rely on contract manufacturers, we have personnel with experience in manufacturing, as well as process development, analytical development, quality assurance and quality control. Under the 2003 Sandoz Collaboration and the 2006 Sandoz Collaboration, Sandoz is responsible for commercialization, including manufacturing, of our Enoxaparin Sodium Injection and M356. Under the Baxter Agreement, Baxter is responsible for commercialization, including the commercial manufacturing, of M923.

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. In order to commercialize any products that are not encompassed by the 2003 Sandoz Collaboration, the 2006 Sandoz Collaboration or the Baxter Agreement, we must either develop a sales, marketing and distribution infrastructure or collaborate with third parties that have sales, marketing and distribution experience, and we will review these options as our other product candidates move closer to commercialization.

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, a biosimilar may also be filed for approval under the new 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 injectables), 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, Sanofi-Aventis filed a Citizen Petition that argued that "sameness" could not be established by any applicant filing an ANDA for a generic Lovenox on the grounds that Lovenox was too complex to be thoroughly characterized. The FDA denied Sanofi-Aventis petition in connection with the approval of the ANDA for Enoxaparin Sodium Injection. 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 BPCI was enacted which created a new abbreviated approval pathway for biosimilars. The new 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 brand product, and the FDA cannot approve a biosimilar version of the brand product until 12 years after the brand 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 new Section 351(k) pathway creates two primary regimes to encourage the development of biosimilars. First, it authorizes the FDA to rely on the safety and efficacy of a brand biologic 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 brand biologic BLA holder. The law defines a biosimilar product as a biologic that:

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

The new 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 brand biologic 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 brand biologic product is no greater than the risk of using the brand biologic product without switching.

The new Section 351(k) pathway states that a biosimilar product that is determined to be interchangeable may be substituted for the brand biologic product without the intervention of a health care provider who prescribed the brand biologic product. The law states that the biosimilar must be for the same indication as the brand biologic, 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. The FDA has not established final guidance on proving similarity or in 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 contemplates well-defined 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 also provides for limited regulatory exclusivity for the first FDA-approved interchangeable biologic with respect to each

originator reference biologic. This means that the FDA will defer approval of additional interchangeable biologics to the same originator biologic for defined periods of one year or more.

Upon filing an abbreviated application, the patent negotiation and clearance process is triggered. Under the provisions, an applicant and the brand biologic company are required to share information to seek to resolve any patent disputes. 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 brand biologic 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 brand biologic company or other patent holders not involved in the prior patent process.

The BPCI 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.

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.

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 added new exclusivity provisions for brand biologics 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 version of the brand product, and the FDA cannot approve a biosimilar version of the brand product until 12 years after the brand 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.

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.

Enoxaparin Sodium Injection—Generic Lovenox

Our Enoxaparin Sodium Injection, marketed in the United States by Sandoz, faces competition from Sanofi's Lovenox, as well as from other generic versions of Lovenox. In October 2011, through its authorized third-party distributor, Sanofi began marketing its generic version of Lovenox. In January 2012, Actavis and Amphastar launched a generic version, and Teva announced that it launched a generic version of Lovenox in February 2015. As a result of this competition, our Enoxaparin Sodium Injection has lost market share and Sandoz has lowered its price. We may face more generic competition as an ANDA has been submitted to the FDA by Hospira, Inc., and other ANDAs or regulatory applications may have been submitted or may be submitted in the future.

In addition to competition from Lovenox and generic versions of Lovenox, our Enoxaparin Sodium Injection faces competition from other anticoagulants used to treat DVT (deep vein thrombosis) and ACS (acute coronary syndrome). These competitive products include Factor Xa inhibitors, Factor IIa inhibitors, other low molecular weight heparin products, and products in clinical development. The Factor Xa inhibitors include: GlaxoSmithKline plc's fondaparinux sodium (Arixtra®), Bristol-Myers Squibb Company's apixaban (Eliquis®), Bayer AG and Johnson & Johnson Pharmaceutical's rivaroxaban (Xarelto®), and Daiichi Sankyo Company's edoxaban (Savaysa®). The FDA-approved Factor IIa inhibitor is Boehringer Ingelheim GmbH's dabigatran etexilate (Pradaxa®).

M356—Generic Copaxone Candidate

If our once-daily 20 mg/mL M356 is approved, it would compete directly with Teva's once-daily formulation of Copaxone. If our three-times-weekly 40 mg/mL M356 is approved, it would compete directly with Teva's three-times-weekly formulation of Copaxone. Teva has reported that since it began marketing its three-times-weekly formulation in early 2014, over 60% of patients previously treated with the once-daily formulation have switched to the three-times-weekly formulation. As a result, the market potential for our once-daily formation of M356 has decreased, and may decrease further as additional patients are converted from once-daily Copaxone to three-times-weekly Copaxone. We would also compete with other generic versions of Copaxone that may be approved in the future by the FDA. ANDAs for generic versions have been submitted to the FDA by Mylan Inc. and Synthon BV and Synthon Pharmaceuticals, Inc. Other ANDAs or other regulatory applications may have been submitted or may be submitted in the future. We would also compete with products 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; and Aubagio (teriflunomide), marketed by Sanofi.

Biosimilars

With the approval of the new biosimilar and interchangeable biologic pathway under Section 351(k) of the Public Health Service Act, many companies, including Sandoz, Mylan/Biocon, Merck KGaA, Fujifilm Kyowo Kirin Bio., Pfizer Inc., Amgen, Epirus Biopharmaceuticals, Boehringer Ingelheim, Oncobiologics, and Teva, 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 the biosimilars business. In addition, many companies have also disclosed development of a biosimilar adalimumab product, notably: Amgen, Sandoz, Samsung Bioepis, Reliance Life Sciences, Fujifilm Kyowo Kirin Bio., Pfizer,

Boehringer Ingelheim, Zydus Cadila, Oncobiologics, Coherus, Merck KGaA, LG Life Sciences, Celltrion, Biocon/Mylan, Epirus Biopharmaceuticals, Genor, Stada/mAbxience. There has been substantial growth in recent years in the number of generic and pharmaceutical companies looking to develop biosimilar versions of protein-based products. Biotechnology and pharmaceutical companies also continue to invest significantly in better understanding their own products or creating improved versions of marketed 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, Sigma Tau Research, and Pfizer are all believed to be developing compounds with a heparin-based mechanism of action. 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, TH-302 from Threshold Pharmaceuticals, and both tarextumab 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.

Our development work focused on Fc biology, which has yielded two named product candidates (an Fc multimer and an anti-FcRn product), faces competition from a number of companies pursuing the same mechanism of action and from other novel mechanisms of action in development. Merck & Co. and Pfizer are also developing an Fc multimer product. Pfizer's compound is in non-clinical development, and Merck's compound is in a phase I clinical trial. Several companies, including UCB, HanAll, Dyax, and arGEN-X, are developing an FcRn targeted monoclonal antibody. UCB's compound is in a phase I clinical trial and the compounds from HanAll, Dyax, and arGEN-X are in non-clinical development.

Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2014, we had 256 employees, including 81 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 2014 was $106.5 million, compared with $104.0 million in 2013 and $80.3 million in 2012.

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, 2014 have come from our collaborators and are based solely on activities in the United States. Our long-lived assets were $30.0 million, $30.3 million and $29.1 million at December 31, 2014, 2013, and 2012, 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, 2014, our accumulated deficit was $369.1 million. We may incur annual operating losses over the next several years as we expand our drug commercialization, development 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 is approved by the FDA, if Teva is successful in the ongoing Copaxone patent litigation by enjoining the manufacture or sale of M356 by Sandoz or in otherwise asserting its alleged patent rights relating to the manufacturing and sale of Copaxone, we and Sandoz may not be able to launch M356 until September 2015, or we may have to pay significant damages if we launch before September 2015.

In July 2012, the United States Federal District Court in the Southern District of New York (the "District Court") issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. See Part I, Item 3 " *Legal Proceedings* " below in this Annual Report on Form 10-K. The Orange Book-listed patents and one non-Orange Book-listed patent expired on May 24, 2014, however one non-Orange Book-listed patent does not expire until September 1, 2015. In July 2012, we appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in July 2013, the CAFC issued a written opinion invalidating several of the nine patents, including the one patent set to expire in September 2015. Teva appealed the CAFC decision to the Supreme Court of the United States, which in January 2015, vacated the CAFC's 2013 decision and remanded the case to the CAFC to reconsider and rule on the validity of the patent.

Should Teva succeed in the District Court, or succeed in a similar request at the CAFC, the launch of M356, if approved, may not occur until the earlier of a finding of invalidity at the CAFC on remand or September 2015, which would impair our ability to commercialize M356 and harm our business and financial condition. Furthermore, if M356 is approved by the FDA prior to a decision in the patent case, and we and Sandoz launch prior to such decision, and Teva is ultimately successful, we and Sandoz may be liable for significant damages 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 resolution of the patent litigation. In addition, we may not be able to utilize M356 cash flows to support program investments until the conclusion of the lawsuit, which would limit our ability to invest in ongoing R&D programs or require us to raise capital through equity or debt offerings.

If other generic versions of the brand name drugs, or other biosimilars of the reference originator biologics, for which we have products or product candidates, including M356 and M923, are approved and successfully commercialized, our business would suffer.

Generic versions of our products 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, in September 2009, Mylan announced that the FDA had accepted for filing its ANDA for generic Copaxone and in 2011 Synthon announced that it submitted an ANDA to the FDA for a generic Copaxone. 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 generic or biosimilar product offerings, including M356, 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 improved version of a reference brand product, such as Copaxone, is developed that has a new product profile and labeling, the improved version of the product could significantly reduce the market share of the original reference brand product, and may cause a significant decline in sales or potential sales of our generic and biosimilar products.

Brand companies may develop improved versions of a reference brand product as part of a life cycle extension strategy, and may obtain approval of the improved version under a supplemental new drug application, for a drug, or biologics license application for a biologic. Should the brand company succeed in obtaining an approval of an improved 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, in January 2014, Teva's three-times-a-week formulation of Copaxone received marketing approval by FDA. Teva has reported that over 60% of patients previously using its once-daily formulation have converted to its three-times-weekly formulation. As a result, the market potential for our once-daily formation of M356 has decreased, and may decrease further as additional patients are converted from once-daily Copaxone to three-times-weekly Copaxone. In addition, the improved 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 improved product for some period of time. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

If the market for a reference brand product, such as Copaxone, significantly declines, sales or potential sales of our 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.

Teva may allege that we are infringing existing, additional issued or pending patents they hold. 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 delay our launch of M356, if approved, and may have a material adverse effect on our business.

Teva may assert existing, additional issued or pending patents, and it may claim that we are infringing those patents, including in connection with the on-going Copaxone patent litigation. We expect to continue to incur significant expenses to respond to and litigate these claims. 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 marketing and selling M356. Furthermore, we may be ordered to pay damages, potentially including treble damages, if we launch M356 prior to a decision of the patent case and are subsequently found to have willfully infringed Teva's patent rights. Litigation concerning intellectual property and proprietary technologies is widespread and can be protracted and expensive, and can distract management and other key personnel from running our business.

If we were unsuccessful in any additional patent suits brought by Teva, we may be unable to effectively market M356, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

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.

As of December 31, 2014, we had cash, cash equivalents and marketable securities totaling $191.5 million. For the year ended December 31, 2014, we had a net loss of $98.6 million and cash used in operating activities of $65.2 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 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 Enoxaparin Sodium Injection;
- our ability to utilize any M356 cash flows, in whole or in part, generated before or after resolution of the Copaxone patent case;
- whether a final decision, after appeal, is issued in favor of Teva in its Copaxone-related patent infringement litigation matters against us;
- the timing of the approval, launch and commercialization of our product candidates, including M356;
- the advancement of our product candidates and other development programs, including the timing and costs of obtaining regulatory approvals;
- the advancement of our biosimilar product candidates and receipt of license and milestone payments under our Baxter Agreement;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation, including with Amphastar and Actavis 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 strategic 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 potential acquisition and in-licensing of 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 expenditure requirements principally through our current cash, cash equivalents and marketable securities and capital raised through equity financings, including utilization of our At-the-Market facility. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2015. 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 could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

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 certain of 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 alliances may involve the other company purchasing a significant number of shares of our common stock. For example, one of our current collaboration partners, through an affiliate, acquired shares in connection with entering into our collaboration which currently represent approximately 9% of our shares of common stock outstanding. 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 current 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's 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 of Enoxaparin Sodium Injection, which will therefore impact our product revenue. Furthermore, other

competitors may in the future receive approval to market generic enoxaparin products which would further impact our product revenue.

Due to these circumstances, the resulting market price for our Enoxaparin Sodium Injection product has decreased and may decrease further, and we have lost market share and may continue to lose market share for Enoxaparin Sodium Injection. All of this may further impact our revenue from Enoxaparin Sodium Injection and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer.

If our patent litigation against Amphastar related to Enoxaparin Sodium Injection is not successful, we may be liable for damages. In addition, third parties may be able to commercialize generic Lovenox products without risk of patent infringement damages, and our business may be materially harmed.

If we are not successful in the patent litigation against Amphastar and Actavis and do not succeed in obtaining injunctive relief or damages, the reduction in our revenue stream will be permanent and our ability to fund future discovery and development programs may suffer. Furthermore, in the event that we are not successful in our appeal of the District Court decision to grant summary judgment against us, and Amphastar and Actavis are able to prove they suffered damages as a result of the preliminary injunction 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 and Actavis are successful in their motion to increase the amount of the security bond.

In addition, if we are not successful in the patent case against Teva and do not succeed in obtaining injunctive relief or a declaratory judgment, we may lose additional market share for Enoxaparin Sodium Injection. Consequently, our revenue would be reduced and our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer.

If efforts by manufacturers of branded 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;
- 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;
- 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, payors 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 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. To date, Teva Neuroscience, Inc. has filed seven Citizen Petitions regarding M356, of which six have been denied and dismissed and one was withdrawn by Teva. However, Teva may seek to file future petitions and may also seek reversal of the denial of a Citizen Petition in federal court. Other third parties may also file Citizen Petitions requesting that the FDA adopt specific approval standards for generic or biosimilar products. If the FDA grants future Citizen Petitions, we and Sandoz may be delayed in obtaining, or potentially unable to obtain, approval of the ANDA for M356 which would 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 the raw materials, including unfractionated heparin, or UFH, used in our products become difficult to obtain, significantly increase in cost or become unavailable, we may be unable to produce our products and this would have a material adverse impact on our business.

We and our collaborative partners and vendors obtain certain raw materials, including UFH, from suppliers who in turn source the materials from other countries, including four suppliers in China. In 2008, due to the occurrence of adverse events associated with the use of UFH, there were global recalls of UFH products, including in the United States, putting our supply chain at risk. Based on investigation by the FDA into those adverse events, the FDA identified a heparin-like contaminant in the implicated UFH products and recommended that manufacturers and suppliers of UFH use additional tests to screen their UFH active pharmaceutical ingredient. We and our collaborative partner worked with the appropriate regulatory authorities to document and to demonstrate that our testing standards meet or exceed all requirements for testing and screening the supply of UFH active pharmaceutical ingredient. The FDA and other authorities have also placed restrictions on the import of some raw materials from China, and may in the future place additional restrictions and testing requirements on the use of raw materials, including UFH, in products intended for sale in the United States. As a result, the raw materials, including UFH, used in our products may become difficult to obtain, significantly increase in cost, or become unavailable to us. If any of these events occur, we and our collaborative partners may be unable to produce our products in sufficient quantities to meet the requirements for the commercial launch or demand for the product, which would have a material adverse impact on our business.

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. In addition, events such as the contamination of UFH may have an adverse impact on the supply of starting or raw materials for some of our products and product candidates, and we, our collaborative partners or our third-party contractors may have difficulty producing products in the quantities necessary to meet FDA requirements or meet anticipated market demand. 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, payors 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 position.

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 products are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. As Enoxaparin Sodium Injection is primarily a hospital-based product, a large percentage of the revenue for Enoxaparin Sodium Injection is derived through contracts with GPOs. Currently, a relatively small number of GPOs control a substantial portion of generic pharmaceutical sales to hospital customers. In order to establish and maintain contracts with these GPOs, we believe that we, in collaboration with Sandoz, will need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products. The GPOs 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 Enoxaparin Sodium Injection to certain hospital segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by our customers, including the GPOs, wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our products. We anticipate that M356 will be primarily distributed through retail channels and mail order services. 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 payors. Acceptance of our products will be a function of our products being clinically useful, being cost effective and demonstrating superior 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 payor 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 commercialization of pharmaceutical products, we may have difficulty managing our growth and expanding our operations successfully.

As we advance our product candidates through the development process, we will need to expand our development, regulatory, manufacturing, quality, distribution, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other organizations. 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 near-term success of our business is significantly dependent on the success of M356. If we are not able to obtain regulatory approval for commercial sale ofM356, 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 December 2007. 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;
- is of the same dosage form, strength and route of administration as Copaxone, and has the same labeling as the approved labeling for Copaxone, with certain exceptions; and
- meets compendial 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 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 are chemical equivalents. In that case, the FDA may require additional information, including nonclinical or clinical test 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.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of Copaxone, 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 similarity or interchangeability for biosimilars are only just being implemented by the FDA. Therefore, substantial uncertainty remains about the potential value our proprietary technology platform can offer to biosimilars development programs.

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. To date, there have been no biosimilar products approved, and, to our knowledge, only a few biosimilar applications have been accepted for review by the FDA, under the 351(k) pathway. The new 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 interchangeable at the retail pharmacy level without the intervention of a physician. The new 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 interchangeability, reduces the need for expensive clinical or other testing, and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a 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 as the agency begins to implement the new law. 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 minimize non-clinical and clinical requirements by relying on analytical data may not be successful or may take longer than strategies that rely more heavily on non-clinical and clinical trial data.

The new 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 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 new 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 new legislation also creates the risk that, as brand and biosimilar companies gain experience with the new 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 new 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 2015 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.

Even if we are able to obtain regulatory approval for our generic and interchangeable biologic 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 reference listed drug. If our generic or interchangeable biologic products are not substitutable at the pharmacy level for their reference listed drugs, 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 development candidates, including necuparanib, are not successful, we will not be able to obtain regulatory approval for commercial sale of our novel or improved drug 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 may not predict the results that will be obtained in 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 payors 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 payors, both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor'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 payor 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 payor. 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 payor will reimburse the use of any drug product incorporating new technology. Even when a payor determines that a product is eligible for reimbursement, the payor 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 payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payors, 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 determines whether to apply generic drug reimbursement approaches or to develop new mechanisms for assigning reimbursement codes to biosimilar products. 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 payors 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 payors 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 payors.

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 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. Enactment of user fee legislation in 2012 is only beginning to fund additional resources and the impact of the new legislation which implements goals and metrics for application review has been reported by the FDA to have had limited impact to this backlog and the delays as it recruits and trains new FDA staff. Until such time as resources are actually increased and in place at the FDA, 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. 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.

There is presently uncertainty regarding the scope of the safe harbor from patent infringement under federal patent law, 35 USC section 271 (e)(1), for activities related to developing and submitting information under a federal law. This uncertainty is especially high for our patents protecting our testing methods. The scope and application of the safe harbor is the subject of our on-going patent litigation with Amphastar. Additional information about this litigation is set forth under Part I, 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 2003 Sandoz Collaboration and 2006 Sandoz Collaboration are important to our business. If Sandoz fails to adequately perform under either collaboration, or if we or Sandoz terminate all or a portion of either collaboration, the development and commercialization of some of our drug candidates, including Enoxaparin Sodium Injection, would be delayed or terminated and our business would be adversely affected.

2003 Sandoz Collaboration

Either we or Sandoz may terminate the 2003 Sandoz Collaboration for material uncured breaches or certain events of bankruptcy or insolvency by the other party. Sandoz may also terminate the 2003 Sandoz Collaboration if the Enoxaparin Sodium Injection product or the market lacks commercial viability, if new laws or regulations are passed or court decisions rendered that substantially diminish

our legal avenues for commercialization of Enoxaparin Sodium Injection, or, in multiple cases, if certain costs exceed mutually agreed upon limits. If the 2003 Sandoz Collaboration is terminated other than due to our uncured breach or bankruptcy, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize Enoxaparin Sodium Injection in the United States. 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 commercializing Enoxaparin Sodium Injection. If Sandoz terminates the 2003 Sandoz Collaboration due to our uncured breach or bankruptcy, Sandoz would retain the exclusive right to commercialize Enoxaparin Sodium Injection in the United States. In that event, we would no longer have any influence over the commercialization strategy of Enoxaparin Sodium Injection in the United States. In addition, Sandoz would retain its rights of first negotiation with respect to certain of our other products in certain circumstances and its rights of first refusal outside of the United States and the European Union.

Accordingly, if Sandoz terminates the 2003 Sandoz Collaboration, we may decide to discontinue the Enoxaparin Sodium Injection program, or our revenue may be reduced, any one of which could have a material adverse effect on our business.

2006 Sandoz Collaboration

Either we or Sandoz may terminate the Second Sandoz Collaboration Agreement for material uncured breaches or certain events of bankruptcy or insolvency by the other party. In addition, either we or Sandoz may terminate some of the products, on a product-by-product basis, if clinical trials are required. For some of the products, for any termination of the Second 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 Second 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 Second 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 Second 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 agreements, we are dependent upon Sandoz to successfully continue to commercialize Enoxaparin Sodium Injection, and if it is approved , we will be dependent on Sandoz to successfully commercialize M356. We do not control Sandoz's commercialization activities or the resources it allocates to our products. Our interests and Sandoz's interests may differ or conflict from time-to-time or we may disagree with Sandoz's 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. If these events were to occur, our business would be adversely affected.

The Baxter Agreement is important to our business. If we or Baxter fail to adequately perform under the Agreement, or if we or Baxter 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 Baxter Agreement may be terminated:

- by either party for breach by the other party (in whole or on a product by product or country-by-country basis);
- by either party for bankruptcy of the other party;
- by Baxter for its convenience;
- by us in the event Baxter 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 Baxter Agreement, in event of such a breach by Baxter; 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 Baxter Agreement were terminated by Baxter for convenience or if Baxter elects to terminate the Baxter Agreement with respect to M923 in the specified time frame or if we terminate the Baxter Agreement for breach by Baxter, 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 our biosimilar candidates. For example, in February 2015, Baxter terminated in part the Baxter Agreement as it relates specifically to M834. As a result, continued development of M834 may be delayed until we can enter into another collaboration to develop that program. Any alternative collaboration could also 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 Baxter terminates the Baxter Agreement due to our uncured breach, Baxter 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 Baxter Agreement, we are dependent upon Baxter to successfully conduct clinical trials for, and if approved, commercialize M923. We do not control Baxter's administration of the clinical trials, commercialization activities or the resources it allocates to M923. Our interests and Baxter's interests may differ or conflict from time to time, or we may disagree with Baxter's level of effort or resource allocation. Baxter 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.

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, 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, or a change in senior executive management within, our 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, for example, 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. 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:

- failure to obtain FDA approval for the M356 20 mg/mL ANDA or other announcements that indicated a delay in the approval of the M356 20 mg/mL ANDA;
- 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 Enoxaparin Sodium Injection to sustain profitable sales or market share that meet expectations of securities analysts;
- other adverse FDA decisions relating to our Enoxaparin Sodium Injection product or M356 program, including an FDA decision to require additional data, including requiring clinical trials, as a condition to M356 20 mg/mL 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 Teva or Amphastar and Actavis in our patent litigation suits, or a settlement related to any case;
- announcements by other companies regarding the status of their ANDAs for generic versions of Lovenox or Copaxone;
- FDA approval of other companies' ANDAs for generic versions of Lovenox or Copaxone;
- marketing and/or launch of other companies' generic versions of Lovenox or 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 launch 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, 2015, 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	08/31/2016
	183,500		

Item 3. LEGAL PROCEEDINGS

M356

On August 28, 2008, Teva 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 Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for a 20 mg/mL formulation of M356. The suit alleged infringement related to four of the seven Orange Book-listed patents for Copaxone and sought declaratory and injunctive relief that would prohibit the launch of our product until the last to expire of these patents. The Orange Book is a publication of the FDA that identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act and includes patents that are purported by the drug application owner to protect each drug. If there is a patent listed for the branded drug in the Orange Book at the time of submission of an ANDA, or at any time before an ANDA is approved, a generic manufacturer's ANDA must include one of four types of patent certifications with respect to each listed patent. We and Sandoz asserted various defenses and filed counterclaims for declaratory judgments to have all seven of the Orange Book patents, as well as two additional patents in the same patent family adjudicated in that lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book-listed patents for Copaxone, and in October 2010, the Court consolidated the Mylan case with the case against us and Sandoz. A trial on the issue of inequitable conduct occurred in July 2011 and the trial on the remaining issues occurred in September 2011 in the consolidated case. In June 2012, the Court issued its opinion and found all of the claims in the patents to be valid, enforceable and infringed. In July 2012, the Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. In July 2012, we appealed the decision to the CAFC, and in July 2013, the CAFC issued a written opinion invalidating several of the nine patents, including one non Orange Book-listed patent which is set to expire in September 2015. The other patents expired on May 24, 2014. The CAFC remanded the case to the District Court to modify the injunction in light of the CAFC decision. In September 2013,

Teva filed a petition for rehearing of the CAFC decision, and in October 2013 the CAFC denied the petition. Teva filed a petition for review by the Supreme Court of the United States in January 2014, and in March 2014 the Supreme Court granted certiorari in the case in order to review the appropriate standard for deference to district court findings in claim construction. Briefing was completed in September 2014, and oral argument was held in October 2014. On January 20, 2015, the Supreme Court vacated the 2013 decision of the CAFC and remanded the case to the CAFC for additional findings to determine the validity of the relevant patent claims that had previously been determined to be invalid. In February 2015, the CAFC ordered the parties to file briefs by March 2, 2015. During the pendency of this litigation any launch of M356 would be a launch at risk of infringement.

Since 2008, Teva has filed seven Citizen Petitions with FDA requesting that FDA deny the approval of any ANDA filed for generic Copaxone. The FDA has denied six of the Citizen Petitions filed by Teva and one was withdrawn by Teva. Teva filed suit against the FDA in the United States District Court for the District of Columbia in May 2014, seeking a court order granting the relief sought in the Citizen Petitions. We and Sandoz intervened in the suit, and following a hearing on a motion for the preliminary injunction, the Court dismissed the case for lack of jurisdiction prior to approval of the ANDA. We anticipate Teva will continue to engage in activities that seek to challenge the approval of our M356 ANDA.

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 a 40 mg/mL formulation of M356. The suit alleges infringement related to two Orange Book-listed patents for 40 mg/mL Copaxone, each expiring in 2030, and seeks declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents. We and Sandoz have asserted various defenses and filed counterclaims for declaratory judgments of non-infringement, invalidity and unenforceability of both patents.

Enoxaparin Sodium Injection

On September 21, 2011, we and Sandoz sued Amphastar, Actavis, and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) 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, Actavis and International Medical Systems, Ltd. 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, Actavis and International Medical Systems, Ltd. 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, Actavis and International Medical Systems, Ltd. appealed the decision to the CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding 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 January 2013, Amphastar and Actavis filed a motion for summary judgment in the District Court following the decision from the CAFC and in July 2013, the District Court granted the motion for summary judgment. We have 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. We opposed this motion and the CAFC denied the motion in May 2014. The CAFC set a briefing schedule which ended in November 2014. We expect the CAFC to hold a hearing on our appeal during the first half of 2015, and we expect a decision in 2015.

In the event that we are not successful in any appeal, and Amphastar and Actavis are able to prove they 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.

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, 2013	$ 14.34	$ 11.86
June 30, 2013	15.25	11.22
September 30, 2013	18.08	13.76
December 31, 2013	18.22	14.26
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

Holders

On February 24, 2015, the approximate number of holders of record of our common stock was 37.

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

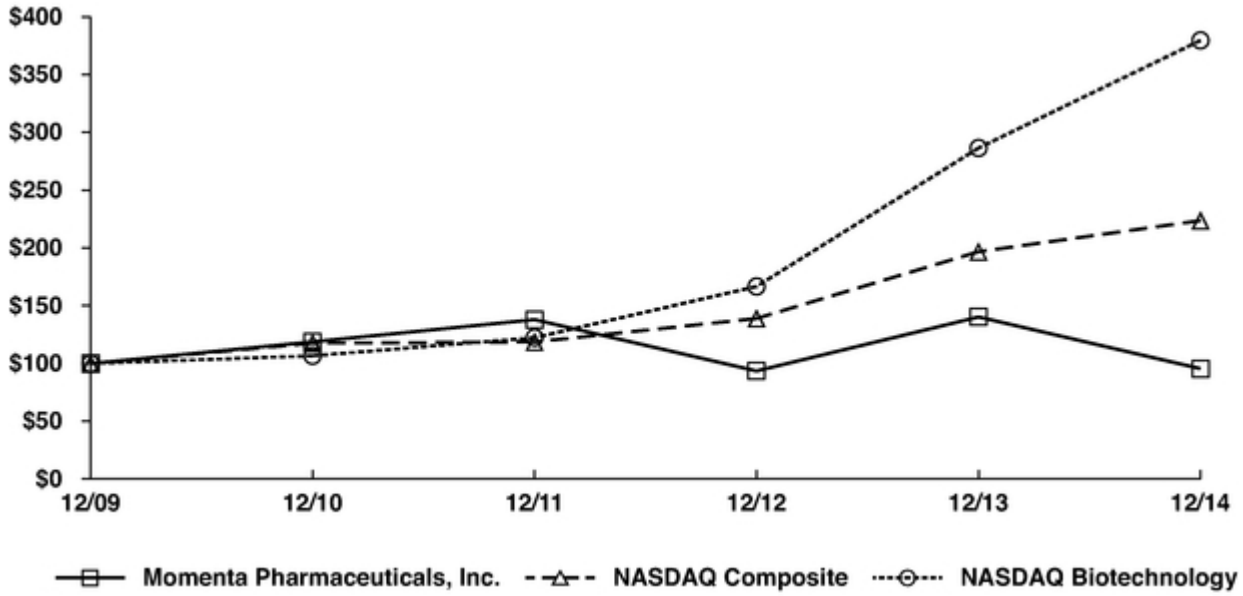
Information relating to compensation plans under which our equity securities are authorized for issuance is set forth in Item 12 below.

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, 2009 through December 31, 2014, 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 12/31/09 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	12/09	12/10	12/11	12/12	12/13	12/14
Momenta Pharmaceuticals, Inc .	**100.00**	**118.81**	**138.02**	**93.57**	**140.32**	**95.56**
NASDAQ Composite	**100.00**	**117.61**	**118.70**	**139.00**	**196.83**	**223.74**
NASDAQ Biotechnology	**100.00**	**106.73**	**122.40**	**166.72**	**286.55**	**379.71**

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, 2014, 2013 and 2012 and the balance sheet data as of December 31, 2014 and 2013 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, 2011 and 2010 and the balance sheet data as of December 31, 2012, 2011 and 2010 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

	2014	2013	2012	2011	2010
	(in thousands, except per share information)				
Statements of Comprehensive (Loss) Income Data:					
Collaboration revenues:					
Product revenue	$ 19,963	$ 16,701	$ 54,772	$ 270,473	$ 96,625
Research and development revenue	32,287	18,764	9,149	12,595	20,147
Total collaboration revenue	52,250	35,465	63,921	283,068	116,772
Operating expenses:					
Research and development	106,482	103,999	80,345	64,657	51,712
General and administrative	45,164	41,057	43,682	38,710	28,595
Total operating expenses	151,646	145,056	124,027	103,367	80,307
Operating (loss) income	(99,396)	(109,591)	(60,106)	179,701	36,465
Interest income	548	950	1,238	746	176
Interest expense	—	—	—	(91)	(329)
Other income	248	233	220	—	978
Net (loss) income	$ (98,600)	$ (108,408)	$ (58,648)	$ 180,356	$ 37,290
Net (loss) income per share:					
Basic	$ (1.91)	$ (2.13)	$ (1.16)	$ 3.62	$ 0.84
Diluted	$ (1.91)	$ (2.13)	$ (1.16)	$ 3.55	$ 0.81
Shares used in calculating net (loss) income per share:					
Basic	51,664	50,907	50,411	49,852	44,626
Diluted	51,664	50,907	50,411	50,823	45,942
Comprehensive (loss) income	$ (98,641)	$ (108,494)	$ (58,456)	$ 180,291	$ 37,281

	As of December 31,				
	2014	2013	2012	2011	2010
Balance Sheet Data:					
Cash and cash equivalents	$ 61,349	$ 29,766	$ 52,990	$ 49,245	$ 100,681
Marketable securities	130,180	215,916	287,613	299,193	52,078
Working capital	181,541	243,649	339,006	383,393	196,650
Total assets	256,216	316,815	406,629	420,909	227,569
Deferred revenue	30,998	27,716	31,695	3,764	5,913
Other liabilities	18,850	19,262	14,447	14,067	15,553
Total liabilities	49,848	46,978	46,142	17,831	21,466
Accumulated deficit	(369,059)	(270,459)	(162,051)	(103,403)	(283,759)
Total stockholders' equity	206,368	269,837	360,487	403,078	206,103

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.

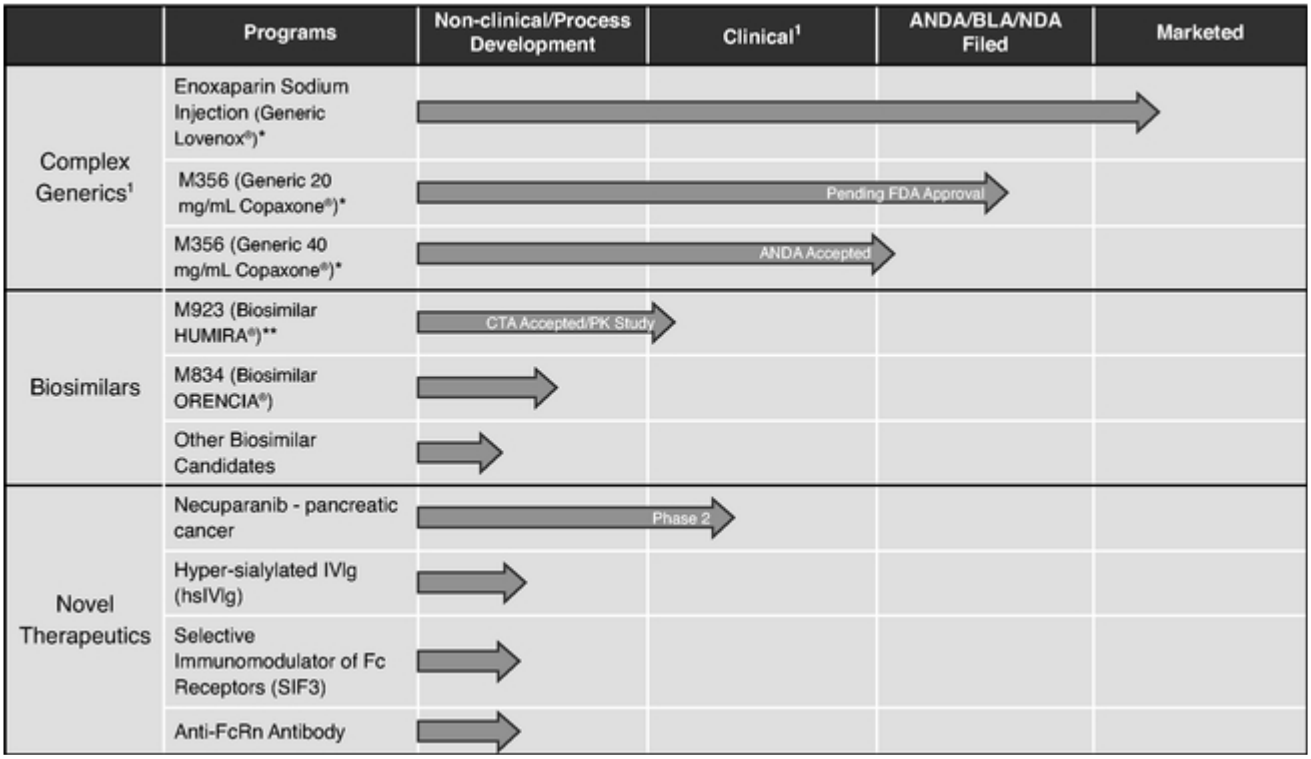
Business Overview

Introduction

We are a biotechnology company focused on developing generic versions of complex drugs, biosimilars and novel therapeutics for oncology and autoimmune disease. 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 believe our complex systems analysis platform gives us a competitive advantage in developing complex generics, biosimilars and novel therapeutics. 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.

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, 2014, we had an accumulated deficit of $369 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.

A summary of our programs in each of our product areas is set forth below.



[1] ***Clinical safety/efficacy trials have not been required for these complex generic drug applications***

****In collaboration with Sandoz***

*****In collaboration with Baxter***

Complex Generics

Enoxaparin Sodium Injection

Excluding contractual adjustments under our collaboration agreement, our royalties on Enoxaparin Sodium Injection decreased from $20.5 million in 2013 to $20.0 million in 2014, on Sandoz net sales of $213 million and $197 million, respectively, for those years. For comparison, Sanofi reported $248 million (€187 million) and $173 million (€130 million) in U.S. sales of Lovenox in 2013 and 2014, respectively. In addition to Sanofi's branded generic, which was launched in October 2011, and the generic product by Actavis and Amphastar, which was launched in January 2012, Teva announced that it launched a generic version of enoxaparin sodium injection in February 2015. We expect continued downward price pressure and decreased market share in the United States for our Enoxaparin Sodium Injection as additional generics enter the market.

M356

Once-daily 20 mg/mL

The ANDA for our once-daily 20 mg/mL formulation of M356, which we submitted in December 2007, continues to be under active review by the FDA. We remain optimistic that we will receive FDA approval in the near future, and we and Sandoz are prepared for a commercial launch of the product in 2015, pending approval.

The lawsuit filed against us by Teva and Yeda Research and Development Co., Ltd, or Yeda, in response to the filing of the ANDA with a Paragraph IV certification for the 20 mg/mL formulation of M356 is on-going. The one patent subject to the suit that has not expired is set to expire in September 2015. We expect a final decision as early as the end of 2015. A description of the proceedings is set

forth under Part I, Item 3 *"Legal Proceedings* ." Prior to the earlier of (i) the final resolution of the lawsuit or (ii) September 2015, any launch of our generic version of once-daily 20 mg/mL Copaxone, if approved, would be at risk of infringing Teva's patent and, if Teva is ultimately successful, we and Sandoz could be liable for significant damages. Under our collaboration agreement, Sandoz has the right to decide whether and when to launch at risk and is evaluating the potential to launch prior to final resolution of the lawsuit. If Sandoz chooses to launch at risk, until the earlier of resolution of the patent litigation or September 2015, we expect to segregate and restrict cash flow we may receive from Sandoz related to our share of contractual profits on Sandoz's sales of M356 for payment of potential damages. If we and Sandoz become liable for damages due to an at-risk launch we are required to pay our contractual portion of the damage amount to Sandoz by deductions of up to 50% of our post-decision M356 revenue, on a quarterly basis, until we have paid our share of the damages.

Teva received marketing approval of its three-times-weekly 40 mg/mL formulation of Copaxone in January 2014 and has reported that over 60% of patients previously using its once-daily 20 mg/mL formulation have converted to its three-times-weekly formulation. As a result, the market potential of our once-daily 20 mg/mL formulation of M356 has decreased, and may decrease further as additional patients are converted from once-daily Copaxone to three-times-weekly Copaxone.

Three-times-weekly 40 mg/mL

In August 2014, an ANDA with a Paragraph IV certification for our generic version of three-times-weekly 40 mg/mL Copaxone was filed with the FDA. If we are successful in our challenge of the patents related to 40 mg/mL Copaxone, and assuming customary patent litigation timelines, we believe our three-times-weekly 40 mg/mL formulation of M356 could be approved, following expiration of any 30-month stay, if applicable, as early as the first quarter of 2017.

Biosimilars

M923

We and Baxter are pursuing a global regulatory strategy for M923. In December 2014, a clinical trial application, or CTA, to initiate a pharmacokinetic clinical trial for M923 was accepted by the UK Medicines and Healthcare Products Regulatory Agency. Acceptance of the CTA met two milestones under the Baxter collaboration, resulting in payment to us of an aggregate of $12.0 million in milestone payments. The trial commenced in the first quarter of 2015. Baxter is planning to submit the first regulatory application for marketing approval for M923 as early as 2017.

M834

M834 was previously being developed and commercialized in collaboration with Baxter. In February 2015, Baxter terminated in part our collaboration as it relates specifically to M834. Prior to termination, in October 2014, we achieved a pre-defined "minimum development criteria" milestone under the Baxter collaboration, resulting in us receiving a license payment of $7.0 million. Following Baxter's termination, we retain all worldwide development and commercialization rights for M834. We plan to continue to develop M834 with a goal of being able to enter clinical development in 2016 and are currently identifying and pursuing potential opportunities to partner the program.

Other Biosimilar Candidates

In addition to M923 and M834, we are also investing in several other, earlier stage biosimilar programs that we believe will allow us to broaden our biosimilar product portfolio and technology base. We seek to identify and collaborate with strategic partners who can bring best-in-class, global commercial capabilities and can help secure high quality, low cost manufacturing and distribution. We

seek to leverage our capabilities and expertise to advance programs to a stage where we can derive optimal stockholder value from each of our collaborations.

In February 2015, Baxter's right to include three additional programs under our collaboration expired without being exercised.

Novel Therapeutics

Necuparanib

In October 2014, we successfully completed Part A and reported positive top-line data from our Phase 1/2 clinical trial in patients with advanced metastatic pancreatic cancer, which we initiated in 2012. We determined a maximum tolerated dose of 5 mg/kg. We believe the safety data and early signals of efficacy from Part A are very encouraging. We believe 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. At this dose level, no significant additional toxicity to what would be expected with the underlying Abraxane / gemcitabine combination was observed. Additionally, as the necuparanib dose was increased across cohorts, no dose proportional trends in adverse events were observed. We believe these results suggest the possibility of combining necuparanib with many other chemotherapy and targeted therapy standards of care in a variety of other tumor types. We plan to present more mature data from Part A in mid-2015.

In October 2014, we initiated Part B, or Phase 2, of the Phase 1/2 trial. We expect data from Phase 2 to be available as early as the end of 2016.

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 our SIF3 and Anti-FcRn programs with a goal of entering both programs into clinical development in late 2016. We are currently identifying and pursuing potential opportunities to partner the further development and commercialization 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.

At-the-Market Facility

In order to preserve our ability to invest in our development pipeline and for other general corporate purposes, in May 2014, we established an At-the-Market financing facility, or ATM, pursuant to which we are authorized to sell up to $75 million of our common stock. Through December 31, 2014, we sold approximately 1.7 million shares of common stock under the ATM, raising net proceeds of approximately $18.3 million. From January 1, 2015 through February 26, 2015, we sold an additional 1.4 million shares of common stock under the ATM, raising net proceeds of approximately $18.5 million.

Results of Operations

Comparison of Years Ended December 31, 2014, 2013 and 2012

Collaboration Revenue

Collaboration revenue includes product revenue and research and development revenue earned under our collaborative arrangements. Product revenue consists of profit share and/or royalties earned from Sandoz on sales of Enoxaparin Sodium Injection following its commercial launch in July 2010. 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 contractual share of these development and other expenses is subject to an annual claw-back adjustment at the end of each product year, and ends with the product year ending June 2015.

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's 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 ending 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's 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 ending June 30, 2013. For the year ended December 31, 2012, we earned $54.8 million in part on a profit share and in part on a royalty on Sandoz's net sales of Enoxaparin Sodium Injection of $451 million. The increase in our product revenue of $3.2 million, or 19%, from the 2013 period to the 2014 period is due to the adjustment to royalties earned as well as a lower annual claw-back adjustment in 2014. The decrease in our product revenue of $38.1 million, or 70%, and the decrease in Sandoz's net sales of $238 million, or 53%, from the 2012 period to the 2013 period are both due to decreased unit sales due to lower market share, and lower prices in response to competitor pricing reductions on enoxaparin.

There are a number of factors that make it difficult for us to predict the magnitude of future Enoxaparin Sodium Injection product revenue, including the impact of generic competition on Sandoz's market share; the pricing of products that compete with Enoxaparin Sodium Injection and other actions taken by our competitors; the inventory levels of Enoxaparin Sodium Injection maintained by wholesalers, distributors and other customers; the frequency of re-orders by existing customers and the change in estimates for product reserves. Accordingly, our Enoxaparin Sodium Injection product revenue in previous quarters may not be indicative of future Enoxaparin Sodium Injection product revenue.

Research and Development Revenue

Research and development revenue generally consists of amounts earned by us:

- under the 2003 Sandoz Collaboration and 2006 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs (all periods presented);
- under the 2006 Sandoz Collaboration for amortization of the equity premium (all periods presented);
- under the Baxter Agreement for reimbursement of research and development services (beginning in the second half of 2013) and reimbursement of development costs (beginning in the second quarter of 2013);

- under the Baxter Agreement for amortization of portion of $33 million upfront payment that was allocated to M923 and M834 (all periods presented); and

- under the Baxter Agreement for license payments and technical development milestones (2014 only).

Research and development revenue for 2014 was $32.3 million, compared with $18.8 million for 2013 and $9.1 million for 2012. 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 the $12.0 million in M923 technical development milestones earned under the Baxter Agreement and recognized as revenue in the fourth quarter of 2014. The increase in research and development revenue of $9.7 million, or 107%, from the 2012 period to the 2013 period is due to an increase in reimbursable M923 expenses incurred in connection with the Baxter Agreement.

We expect collaborative research and development revenue earned by us related to expense reimbursement from Baxter and Sandoz will fluctuate from quarter to quarter in 2015 depending on our research and development activities.

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 non-clinical studies and clinical trials are conducted;

- costs of acquiring originator comparator materials and manufacturing non-clinical 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.

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.

Research and development expense for 2014 was $106.5 million, compared with $104.0 million in 2013 and $80.3 million in 2012. The increase 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 incurred to advance our novel therapeutics research program; $2.1 million in salary, salary-related and stock compensation 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 Part A dose escalation component of the Phase 1/2 trial as well as start-up and patient enrollment costs incurred for Phase 2 of the trial; $1.0 million in laboratory

supplies to support our product candidates; and $0.2 million in depreciation expense due to higher investments in capital equipment in 2012 and 2013. 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 increase of $23.7 million, or 30%, from the 2012 period to the 2013 period primarily resulted from increases of: $14.7 million in process development and third-party contract research costs, of which approximately $13.0 million related to M923; $5.0 million in personnel and related costs associated with our headcount growth to support our programs; $1.4 million in facility related costs due to additional subleased laboratory and office space; $1.3 million in professional fees primarily related to consulting fees to support our programs; and $0.5 million in depreciation expense due to higher investments in capital equipment in 2012 and 2013.

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, 2014, 2013 and 2012. 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, 2014	Year Ended December 31,			Project Inception to December 31, 2014
		2014	2013	2012	
		(in thousands)			
External Costs Incurred by Product Candidate:					
M356—Generic Copaxone® Candidate	ANDAs filed	$ 920	$ 2,525	$ 3,880	$ 48,007
Necuparanib—Oncology Product Candidate	Phase 2	6,739	3,930	5,053	25,074
Biosimilars	Various—see note below	19,583	24,501	7,440	55,522
Other novel therapeutic programs	Discovery	5,213	3,298	1,316	
Internal Costs		74,027	69,745	62,656	
Total Research and Development Expenses		$ 106,482	$ 103,999	$ 80,345	

Biosimilars includes M923, a biosimilar version of HUMIRA® (adalimumab), M834, a biosimilar version of ORENCIA® (abatacept), as well as other biosimilar candidates. A pharmacokinetic clinical trial for M923 commenced in the first quarter of 2015. M834 is in the non-clinical phase of development, and the other biosimilar candidates are in discovery and process development.

The decrease of $1.6 million in 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 $1.4 million in M356 external expenditures from the 2012 period to the 2013 period was primarily due to timing of process development activities, manufacturing and third-party research costs. Our necuparanib external expenditures decreased by $1.1 million from the 2012 period to the 2013 period as we incurred start-up costs for our Phase 1/2 trial in the 2012 period. The increase of $17.1 million in biosimilars external expenditures from the 2012 period to the 2013 period was due to the process development and third-party contract research costs to advance our biosimilars in development. The increase of $2.0 million in other novel therapeutics program external expenditures from the 2012 period to the 2013 period was primarily due to research collaborations we entered into to support our novel therapeutics program.

Research and development internal costs consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation. The increase of $4.3 million from the 2013 period to the 2014 period and the increase of $7.1 million from the 2012 period to the 2013 period were due to additional research and development headcount and related costs in support of our development programs.

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 2014 was $45.2 million, compared with $41.1 million in 2013 and $43.7 million in 2012. The increase 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 salary, salary-related and stock compensation 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 2012 and 2013; and $0.2 million in other fees.

General and administrative expense decreased by $2.6 million, or 6%, from the 2012 period to the 2013 period primarily due to decreased legal fees relating to the Enoxaparin Sodium Injection patent litigation.

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 $0.5 million, $1.0 million and $1.2 million for the years ended December 31, 2014, 2013 and 2012, respectively. The decrease of $0.5 million from the 2013 period to the 2014 period and $0.2 million from the 2012 period to the 2013 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, 2014, 2013 and 2012.

Liquidity and Capital Resources

At December 31, 2014, we had $191.5 million in cash, cash equivalents and marketable securities and $7.4 million in accounts receivable. 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 Actavis, Amphastar and International Medical Systems, Ltd. Our funds at December 31, 2014 were primarily invested in senior debt of government-sponsored enterprises, commercial paper, 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, 2014.

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's sales of Enoxaparin Sodium Injection. Since our inception through December 31, 2014, we have received $424 million through private and public issuances of equity securities. As of December 31, 2014, we had received a cumulative total of $599 million under our collaborations with Sandoz, including $459 million in Enoxaparin Sodium Injection product revenue, and $73 million under our collaboration with Baxter, including a $33 million upfront payment, $21 million in reimbursement of research and development services and costs and $19 million in license and milestone payments.

We expect to finance and manage our planned operating and expenditure requirements principally through our current cash, cash equivalents and marketable securities and capital raised through equity financings, including utilization of our At-the-Market facility. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2015.

	Year Ended December 31,		
	2014	2013	2012
		(in thousands)	
Net cash (used in) provided by operating activities	$ (65,168)	$ (86,832)	$ 8,999
Net cash provided by (used in) investing activities	75,173	58,586	(7,407)
Net cash provided by financing activities	21,578	5,022	2,153
Net increase (decrease) in cash and cash equivalents	$ 31,583	$ (23,224)	$ 3,745

Cash provided by (used in) operating activities

The cash provided by or 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 $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 Baxter Agreement, Baxter 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 Baxter partially offset by amortization of $3.2 million of revenue from the $33.0 million Baxter upfront payment 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 Baxter 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 Baxter 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 in connection with the Baxter Agreement; 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 Baxter upfront payment; the receipt of $0.7 million from our landlord for leasehold improvements constructed to our leased space at 320 Bent Street; a decrease in other current liabilities of $0.3 million due to the amortization of a deferred rent liability; and a decrease in other long-term liabilities of $0.2 million due to the annual amortization of a job creation tax award.

Cash provided by operating activities was $9.0 million for the year ended December 31, 2012 reflecting a net loss of $58.6 million, which was partially offset by non-cash charges of $7.5 million for depreciation and amortization of property, equipment and intangible assets, $13.7 million for share-based compensation and $3.3 million for amortization of purchased premiums on our marketable securities. In addition, the net change in our operating assets and liabilities provided cash of $43.1 million and resulted from: a decrease in accounts receivable of $17.4 million, due to a contractual change in the basis of calculating our Enoxaparin Sodium Injection product revenue, related to the launch of a competitor's generic Lovenox in January 2012, aggressive competitor pricing, significant adjustments to reserve accruals caused by increased competition and continued pricing pressure, and a decrease in units sold; a decrease in unbilled revenue of $1.9 million, due to lower reimbursable manufacturing activities for our M356 program; an increase in prepaid expenses and other current

assets of $2.4 million, primarily due to a $1.1 million receivable for a job creation tax award, an increase in interest accrued on our available-for-sale marketable debt securities and advance payments made to contract research organizations for nonclinical studies for our M923 program; an increase in restricted cash of $2.5 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 675 West Kendall Street; a decrease in accounts payable of $1.1 million, resulting from the timing of Massachusetts Institute of Technology royalty payments; an increase in accrued expenses of $0.5 million due to payments due to contract research organizations for process development, manufacturing and clinical trial activities in support of our biosimilars, novel products, and necuparanib programs, offset by decreased Massachusetts Institute of Technology royalty payments and legal fees relating to Enoxaparin Sodium Injection patent litigation; and an increase in deferred revenue of $27.9 million, primarily due to the receipt of a $33.0 million upfront payment under the Baxter Agreement.

Cash provided by (used in) investing activities

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 used in investing activities of $7.4 million for the year ended December 31, 2012 includes cash inflows of $523.6 million from maturities of marketable securities offset by cash outflows of $515.1 million for purchases of marketable securities and $15.5 million for capital equipment and leasehold improvements.

Cash provided by financing activities

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 and $2.2 million for the years ended December 31, 2013 and 2012, respectively, relate to stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2014 (in thousands):

Contractual Obligations	Total	2015	2016 through 2017	2018 through 2019	After 2019
License maintenance obligations	$ 1,163	$ 233	$ 465	$ 465	*
Operating lease obligations	26,898	11,177	14,113	1,608	$ —
Total contractual obligations	$ 28,061	$ 11,410	$ 14,578	$ 2,073	$ —

* After 2019, 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.

In July 2010, Sandoz began the commercial sale of Enoxaparin Sodium Injection. From July 2010 through early October 2011, Enoxaparin Sodium Injection marketed by Sandoz was the sole generic version of Lovenox, and consequently, under the terms of our collaborative agreement with Sandoz, we earned 45% of contractual profits from Sandoz's sales of Enoxaparin Sodium Injection. Sanofi launched their authorized generic Lovenox in October 2011 and Actavis and Amphastar launched their enoxaparin product in January 2012 launch. The resulting competition changed the contractual basis of our earned product revenues from profit share to royalty-based. Consequently, beginning in February 2012, for net sales of enoxaparin up to a pre-defined sales threshold, Sandoz is obligated to pay us a royalty on net sales at a 10% rate, and for net sales above the sales threshold, at a 12% rate. We have recorded product revenue on Sandoz's sales of Enoxaparin Sodium Injection. 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.

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, 2014 and December 31, 2013.

During the years ended December 31, 2014 and 2013, 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, 2014 and December 31, 2013. 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 non-clinical 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 2011, except to the extent that in the future we utilize net operating losses or tax credit carryforwards that originated before 2011. As of December 31, 2014, our U.S. 2012 federal tax return is under examination by the Internal Revenue Service.

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, 2014, 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, 2014 and 2013, 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, 2014. 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, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, 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, 2014, 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 27, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 27, 2015

MOMENTA PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 61,349	$ 29,766
Marketable securities	130,180	215,916
Accounts receivable	7,427	13,095
Unbilled revenue	2,909	3,413
Prepaid expenses and other current assets	3,465	3,401
Total current assets	205,330	265,591
Property and equipment, net	25,422	24,699
Restricted cash	20,719	20,719
Intangible assets, net	4,589	5,650
Other long-term assets	156	156
Total assets	$ 256,216	$ 316,815
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,433	$ 6,307
Accrued expenses	10,348	11,447
Deferred revenue	5,490	3,692
Other current liabilities	518	496
Total current liabilities	23,789	21,942
Deferred revenue, net of current portion	25,508	24,024
Other long-term liabilities	551	1,012
Total liabilities	49,848	46,978
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Preferred stock, $0.01 par value per share; 5,000 shares authorized at December 31, 2014 and 2013, 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, 2014 and 2013, 54,486 and 52,357 shares issued and outstanding at December 31, 2014 and 2013, respectively	5	5
Additional paid-in capital	575,438	540,266
Accumulated other comprehensive (loss) income	(16)	25
Accumulated deficit	(369,059)	(270,459)
Total stockholders' equity	206,368	269,837
Total liabilities and stockholders' equity	$ 256,216	$ 316,815

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,		
	2014	2013	2012
Collaboration revenues:			
Product revenue	$ 19,963	$ 16,701	$ 54,772
Research and development revenue	32,287	18,764	9,149
Total collaboration revenue	52,250	35,465	63,921
Operating expenses:			
Research and development*	106,482	103,999	80,345
General and administrative*	45,164	41,057	43,682
Total operating expenses	151,646	145,056	124,027
Operating loss	(99,396)	(109,591)	(60,106)
Other income:			
Interest income	548	950	1,238
Other income	248	233	220
Total other income	796	1,183	1,458
Net loss	$ (98,600)	$ (108,408)	$ (58,648)
Net loss per share:			
Basic and diluted	$ (1.91)	$ (2.13)	$ (1.16)
Weighted average shares outstanding:			
Basic and diluted	51,664	50,907	50,411
Comprehensive loss:			
Net loss	$ (98,600)	$ (108,408)	$ (58,648)
Net unrealized holding (losses) gains on available-for-sale marketable securities	(41)	(86)	192
Comprehensive loss	$ (98,641)	$ (108,494)	$ (58,456)
* Non-cash share-based compensation expense included in operating expenses is as follows:			
Research and development	$ 6,204	$ 5,520	$ 5,832
General and administrative	$ 7,390	$ 7,302	$ 7,880

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 (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balances at December 31, 2011	51,285	$ 5	$ 506,557	$ (81)	$ (103,403)	$ 403,078
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	253	—	2,153	—	—	2,153
Issuance of restricted stock	198	—	—	—	—	—
Cancellation of restricted stock	(27)	—	—	—	—	—
Share-based compensation expense for employees	—	—	13,615	—	—	13,615
Share-based compensation expense for non-employees	—	—	97	—	—	97
Unrealized gain on marketable securities	—	—	—	192	—	192
Net loss	—	—	—	—	(58,648)	(58,648)
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

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,		
	2014	2013	2012
Cash Flows from Operating Activities:			
Net loss	$ (98,600)	$ (108,408)	$ (58,648)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization of property and equipment	7,637	7,108	6,419
Share-based compensation expense	13,594	12,822	13,712
Amortization of premium on investments	2,162	3,575	3,288
Amortization of intangibles	1,061	1,061	1,061
Impairment of equity investment	—	244	—
Loss on disposal of assets	—	23	19
Changes in operating assets and liabilities:			
Accounts receivable	5,668	(2,284)	17,360
Unbilled revenue	504	(2,613)	1,965
Prepaid expenses and other current assets	(64)	1,552	(2,406)
Restricted cash	—	(748)	(2,471)
Other long-term assets	—	—	389
Accounts payable	1,126	2,727	(1,129)
Accrued expenses	(1,099)	1,806	510
Deferred revenue	3,282	(3,979)	27,931
Deferred lease incentives	—	747	—
Other current liabilities	22	(267)	482
Other long-term liabilities	(461)	(198)	517
Net cash (used in) provided by operating activities	(65,168)	(86,832)	8,999
Cash Flows from Investing Activities:			
Purchase of equity investment	—	—	(400)
Purchases of property and equipment	(8,360)	(9,450)	(15,491)
Purchases of marketable securities	(111,809)	(229,969)	(515,088)
Proceeds from maturities of marketable securities	195,342	294,183	523,572
Proceeds from sales of marketable securities	—	3,822	—
Net cash provided by (used in) investing activities	75,173	58,586	(7,407)
Cash Flows from Financing activities:			
Net proceeds from issuance of common stock under ATM facility	18,305	—	—
Proceeds from issuance of common stock under stock plans	3,273	5,022	2,153
Net cash provided by financing activities	21,578	5,022	2,153
Increase (decrease) in cash and cash equivalents	31,583	(23,224)	3,745
Cash and cash equivalents, beginning of period	29,766	52,990	49,245
Cash and cash equivalents, end of period	$ 61,349	$ 29,766	$ 52,990

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 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 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, 2014 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, 2014, 2013 and 2012. Realized gains on marketable securities for the year ended December 31, 2013 were immaterial. There were no realized gains or losses on marketable securities during the years ended December 31, 2014 or 2012. 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, 2014 and 2013.

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, 2014 and December 31, 2013.

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, 2014 and December 31, 2013 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, 2014 and December 31, 2013 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, 2014.

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, 2014 and 2013.

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 2011, except to the extent that in the future it utilizes net operating losses or tax credit carry forwards that originated before 2011. As of December 31, 2014, the Company's U.S. federal tax return for 2012 is under examination by the Internal Revenue Service.

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. See the consolidated statements of comprehensive loss for relevant disclosures.

The following tables summarize the changes in accumulated other comprehensive income (loss) during the years ended December 31, 2014 and December 31, 2013 (in thousands):

	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)

	Unrealized Gains (Losses) on Securities Available for Sale
Balance as of January 1, 2013	$ 111
Other comprehensive loss before reclassifications	(83)
Amounts reclassified from accumulated other comprehensive income	(3)
Net current period other comprehensive loss	(86)
Balance as of December 31, 2013	$ 25

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, or ASU 2014-09, which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. The new standard will be effective for the Company on January 1, 2017. The Company is currently evaluating the method of adoption and the potential impact that ASU 2014-09 may have 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, 2014 and December 31, 2013, 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, 2014 and December 31, 2013 are summarized as follows (in thousands):

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	$ —

Description	Balance as of December 31, 2013	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 24,841	$ 24,841	$ —	$ —
Marketable securities:				
U.S. Government-sponsored enterprise obligations	22,309	—	22,309	—
Corporate debt securities	110,158	—	110,158	—
Commercial paper obligations	20,996	—	20,996	—
Foreign government bonds	26,793	—	26,793	—
Asset-backed securities	35,660	—	35,660	—
Total	$ 240,757	$ 24,841	$ 215,916	$ —

For the years ended December 31, 2014 and 2013, 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, 2014 and December 31, 2013.

4. Cash, Cash Equivalents and Marketable Securities

The following tables summarize the Company's cash, cash equivalents and marketable securities as of December 31, 2014 and December 31, 2013 (in thousands):

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

As of December 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 29,766	$ —	$ —	$ 29,766
U.S. Government-sponsored enterprise obligations				
Due in one year or less	11,000	3	—	11,003
Due in two years or less	11,303	3	—	11,306
Corporate debt securities				
Due in one year or less	94,659	13	(14)	94,658
Due in two years or less	15,498	9	(7)	15,500
Commercial paper obligations due in one year or less	20,978	18	—	20,996
Foreign government bonds				
Due in one year or less	26,782	13	(2)	26,793
Asset-backed securities				
Due in one year or less	26,550	2	(4)	26,548
Due in two years or less	9,121	—	(9)	9,112
Total	$ 245,657	$ 61	$ (36)	$ 245,682
Reported as:				
Cash and cash equivalents	$ 29,766	$ —	$ —	$ 29,766
Marketable securities	215,891	61	(36)	215,916
Total	$ 245,657	$ 61	$ (36)	$ 245,682

At December 31, 2014 and December 31, 2013, the Company held 44 and 28 marketable securities, respectively, which were in a continuous unrealized loss position for less than one year. At December 31, 2014, there was one marketable security in a continuous unrealized loss position for greater than one year. At December 31, 2013, no marketable securities were 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, 2014 and December 31, 2013 (in thousands):

	As of December 31, 2014		As of December 31, 2013	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate debt securities:				
Due in one year or less	$ 63,221	$ (24)	$ 38,508	$ (14)
Due in two years or less	$ —	$ —	$ 11,696	$ (7)
Foreign government bonds:				
Due in one year or less	$ 12,773	$ (1)	$ 6,203	$ (2)
Asset-backed securities:				
Due in one year or less	$ 25,742	$ (9)	$ 16,977	$ (4)
Due in two years or less	$ —	$ —	$ 9,112	$ (9)
U.S. Government-sponsored enterprise obligations:				
Due in two years or less	$ —	$ —	$ 7,303	$ —*

* Less than $1,000

5. Property and Equipment

As of December 31, 2014 and December 31, 2013, property and equipment, net consists of the following (in thousands):

	2014	2013	Depreciable Lives
Computer equipment	$ 2,005	$ 1,742	3 years
Software	9,001	7,221	3 years
Office furniture and equipment	2,436	2,379	5 to 6 years
Laboratory equipment	40,626	35,919	7 years
Leasehold improvements	12,735	11,350	Shorter of asset life or lease term
Less: accumulated depreciation	(41,381)	(33,912)	
	$ 25,422	$ 24,699	

During 2014 and 2013, the Company disposed of laboratory equipment with total gross carrying amount of $168,000 and $66,000, respectively, and accumulated depreciation of $168,000 and $43,000, respectively. Depreciation and amortization expense amounted to $7.6 million, $7.1 million and $6.4 million for the years ended December 31, 2014, 2013 and 2012, 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 developed technology of approximately 10 years. As of December 31, 2014 and December 31, 2013, intangible assets, net of accumulated amortization, are as follows (in thousands):

	Weighted-Average Amortization Period (in years)	2014 Gross Carrying Amount	2014 Accumulated Amortization	2013 Gross Carrying Amount	2013 Accumulated Amortization
Total intangible assets for core and developed technology and non-compete agreement	10	$ 10,427	$ (5,838)	$ 10,427	$ (4,777)

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, 2014, 2013 and 2012.

The Company expects to incur amortization expense of appropriately $1.1 million per year for each of the next four years (2015 to 2018) and $0.3 million in the fifth year (2019).

7. Restricted Cash

The Company designated $17.5 million as collateral for a security bond posted in the litigation against Amphastar Pharmaceuticals Inc., or Amphastar, Actavis, Inc., or Actavis (formerly Watson Pharmaceuticals Inc.), and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar), 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 $2.5 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, 2014 and December 31, 2013, accrued expenses consisted of the following (in thousands):

	2014	2013
Accrued compensation	$ 6,912	$ 6,696
Accrued contracted research costs	2,031	2,480
Accrued professional fees	828	1,170
Accrued royalties	165	158
Other	412	943
	$ 10,348	$ 11,447

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 collaborative arrangements, as defined in the Financial Accounting Standards Board's Accounting Standards Codification Topic 808, *Collaborative Arrangements* . The Company does not have any insignificant collaborative arrangements.

	For the Year Ended December 31, 2014 (in thousands)			
	2003 Sandoz Collaboration	2006 Sandoz Collaboration	Baxter 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	2006 Sandoz Collaboration	Baxter 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

	For the Year Ended December 31, 2012 (in thousands)			
	2003 Sandoz Collaboration	2006 Sandoz Collaboration	Baxter Agreement	Total Collaborations
Collaboration revenues:				
Product revenue	$ 54,772	$ —	$ —	$ 54,772
Research and development revenue:				
Amortization of upfront payments	—	2,156	2,913	5,069
Research and development services and external costs	3,851	229	—	4,080
Total research and development revenue	$ 3,851	$ 2,385	$ 2,913	$ 9,149
Total collaboration revenues	$ 58,623	$ 2,385	$ 2,913	$ 63,921
Operating expenses:				
Research and development expense(1)	$ 1,562	$ 3,880	$ 6,545	$ 11,987
General and administrative expense(1)	$ 355	$ 394	$ 489	$ 1,238
Total operating expenses	$ 1,917	$ 4,274	$ 7,034	$ 13,225

(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

In 2003, the Company entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz 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 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, 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.

The Company is paid at cost for external costs incurred for commercial and related activities and is paid for full time equivalents, or FTEs, performing commercial and related services.

In July 2010, Sandoz began the commercial sale of Enoxaparin Sodium Injection. Under the 2003 Sandoz Collaboration, Sandoz is obligated to pay the Company a contractually defined profit share or a contractually defined royalty based on whether (i) there are no third-party competitors marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), (ii) a Lovenox-Equivalent Product is being marketed by Sanofi-Aventis, which distributes the brand name Lovenox, or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, or (iii) there are one or more third-party competitors which are not Sanofi-Aventis marketing a Lovenox-Equivalent Product. From July 2010 through September 2011, no third-party competitor was marketing a Lovenox-Equivalent Product; therefore, during that period, Sandoz paid the Company 45% of the contractual profits from the sale of Enoxaparin Sodium Injection. In September 2011, FDA approved the ANDA for the enoxaparin

product of Amphastar Pharmaceuticals, Inc., or Amphastar. In October 2011, Sandoz confirmed that an authorized generic Lovenox-Equivalent Product was being marketed, which meant that Sandoz was obligated to pay the Company a royalty on its net sales of Enoxaparin Sodium Injection until the contractual profits from those net sales in a product year (July 1—June 30) reached a certain threshold. Upon achievement of the contractual profit threshold in December 2011, Sandoz was obligated to pay the Company a profit share for the remainder of the product year. In January 2012, following the grant by the Court of Appeals for the Federal Circuit, or CAFC, of a stay of the preliminary injunction previously issued by the United States District Court for the District of Massachusetts, Actavis Inc. (formerly Watson Pharmaceuticals, Inc.), or Actavis, announced that they and Amphastar launched their enoxaparin product. Consequently, in each product year, for net sales of enoxaparin up to a pre-defined sales threshold, Sandoz is obligated to pay the Company a royalty on net sales at a 10% rate, and for net sales above the sales threshold, at a 12% rate. See "Product revenue" in the tables above for product revenue earned by the Company on Sandoz's net sales of Enoxaparin Sodium Injection.

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

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.

Certain development and legal expenses may reduce the amount of profit-share, royalty and milestone payments paid to the Company by Sandoz. Any product liability costs and certain other expenses arising from patent litigation may also reduce the amount of profit-share, royalty and milestone payments paid to the Company by Sandoz, but only up to 50% of these amounts due to the Company from Sandoz each quarter. The contractual share of these development and other expenses is subject to an annual adjustment at the end of each product year, and ends with the product year ending June 2015. Annual adjustments are recorded as a reduction in product revenue at the end of each product year which corresponds to the second quarter of the Company's fiscal year. The annual adjustment of $2.2 million for the 2014 product year 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 2013 product year.

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. See "Research and development revenue" in the tables above for research and development revenue earned by the Company under the 2003 Sandoz Collaboration.

2006 Sandoz Collaboration

In 2006 and 2007, the Company entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement, with Novartis Pharma AG, and a collaboration and license agreement, as amended, or the Second Sandoz Collaboration Agreement, with Sandoz AG. Together, this series of agreements is referred to as the 2006 Sandoz Collaboration. Under the Second Sandoz Collaboration Agreement, the Company and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356, among other products. Further, under the Second Sandoz Collaboration Agreement, the Company and Sandoz AG expanded the geographic markets for

Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union. Under the Stock Purchase Agreement, the Company sold 4,708,679 shares of common stock to Novartis Pharma AG at a per share price of $15.93 (the closing price of the Company's common stock on the NASDAQ Global Market was $13.05 on the date of the Stock Purchase Agreement) for an aggregate purchase price of $75.0 million, resulting in a paid premium of $13.6 million, which 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.

Under the Second Sandoz Collaboration Agreement, costs, including development costs and the costs of clinical studies, will be borne by the Company and Sandoz AG in varying proportions depending on the type of expense and the related product. For M356, the Company is generally responsible for all of the development costs in the United States. For M356 outside of the United States and for Enoxaparin Sodium Injection in the European Union, the Company shares development costs in proportion to its profit sharing interest. All commercialization responsibilities will be borne by Sandoz AG worldwide as they are incurred for all products. The Company and Sandoz AG will share profits in varying proportions, depending on the product. Upon commercialization, the Company will earn a 50% contractual profit share on worldwide net sales of M356. Profits on net sales of M356 will be 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. The Company is reimbursed at cost 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 AG. Sandoz AG is responsible for funding all of the legal expenses incurred under the Second Sandoz Collaboration Agreement; however a portion of certain legal expenses, including any patent infringement damages, will be offset against the profit-sharing amounts in proportion to the Company's profit sharing interest. The Company is eligible to receive up to $163.0 million in milestone payments upon the achievement of certain regulatory, commercial and sales-based milestones for M356 in the United States and Enoxaparin Sodium Injection in the European Union. The M356 milestone payments include a $10.0 million regulatory milestone payment earned upon sole approval by the FDA of M356 in the United States, a $10.0 million milestone payment upon first commercial sale of M356 in the United States and up to $120.0 million in additional milestone payments upon the achievement of certain U.S. commercial and sales-based milestones for M356. The Company is eligible to receive up to $23.0 million in sales-based and commercial milestones for Enoxaparin Sodium Injection in the European Union. None of these payments, once received, is refundable and there are no general rights of return in the arrangement. Sandoz AG 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. As of December 31, 2014, the Company has not earned and therefore has not recognized any milestone payments under this arrangement.

The term of the Second 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 Second Sandoz Collaboration Agreement. The Second Sandoz Collaboration Agreement may be terminated if either party breaches the Second Sandoz Collaboration Agreement or files for bankruptcy. In addition, either the Company or Sandoz AG may terminate the Second Sandoz Collaboration Agreement as it relates to the remaining products, on a product-by-product basis, if clinical trials are required.

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.

Baxter Agreement

In December 2011, the Company entered into a global collaboration and license agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, "Baxter") to develop and commercialize biosimilars. The Company refers to this agreement as the Baxter Agreement. The Baxter Agreement became effective in February 2012.

Under the Baxter Agreement, the Company and Baxter agreed to collaborate, on a world-wide basis, on the development and commercialization of two biosimilars, M923, a biosimilar of HUMIRA® (adalimumab), and M834, a biosimilar of ORENCIA® (abatacept). . In addition, Baxter had the right to select four additional originator biologics to target for biosimilar development under the collaboration. In July 2012, Baxter selected an additional product, a monoclonal antibody for oncology, for which the Company developed a biosimilar program designated as M511. In December 2013, Baxter terminated its option to license M511 under the Baxter Agreement following an internal portfolio review. In February 2015, Baxter's right to select additional programs expired without further exercise. Also in February 2015, Baxter terminated in part the Baxter Agreement as it relates specifically to M834. The Company retains all worldwide development and commercialization rights for M834. The Baxter Agreement remains in effect and unchanged with respect to M923.

Under the Baxter 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 IND or equivalent application in the European Union for M923. Development and related services include high-resolution analytics, characterization, and product and process development. Baxter 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 Baxter, 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 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 Baxter.

Baxter has a right of first negotiation with respect to collaborating with the Company on the development of any product candidate competing with M923. This right is effective for a period of three years following the effectiveness of an IND exemption or waiver or regulatory authority authorization to dose humans, subject to certain restrictions as outlined in the Baxter 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 Baxter's clinical trial application to initiate a pharmacokinetic clinical trial for M923. The Company is eligible to receive from Baxter, 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, Baxter 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 Baxter Agreement.

The Baxter Agreement may be terminated by:

- either party for breach by or bankruptcy of the other party;
- Baxter for its convenience; or
- the Company in the event Baxter 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 Baxter Agreement, in event of such a breach by Baxter.

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 Baxter Agreement. The deliverables were determined to include (i) the development and product licenses to the two initial biosimilars (M923 and M834) and the four additional biosimilars, (ii) the research and development services related to the two initial biosimilars and the four additional biosimilars 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, Baxter does not have the contractual right to resell the license, and Baxter 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 Baxter and market rates for similar services. At the inception of the Baxter Agreement, the arrangement consideration of $61.0 million, which included the $33.0 million upfront payment and aggregate option payments for the four additional biosimilars 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 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 Baxter 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. 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 a result of Baxter's termination of its option to license M511 in December 2013, the expected consideration to be received under the arrangement was reduced by $7.0 million (the potential option payment for M511) as the number of deliverables decreased from six deliverables to five deliverables. The Company determined that the change in expected consideration to be received under the arrangement represented a change in estimate and, as a result, the Company reallocated the revised expected consideration of $54.0 million to the remaining deliverables under the agreement using the original best estimate of selling price. Of the $54.0 million, $11.0 million was allocated to the M923 product license together with the related research and development services, $11.0 million to each of the three additional product licenses with the related research and development services, $10.0 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 $122,000 was allocated to the joint steering committee unit of accounting.

In October 2014, the Company achieved pre-defined "minimum development criteria" for M834 and earned a $7.0 million license payment. The license payment was accounted for as part of the upfront fees and the expected consideration to be received under the arrangement increased from $54.0 million to $61.0 million. The Company reallocated the revised expected consideration of $61.0 million to the remaining deliverables under the agreement using the original best estimate of selling price. Of the $61.0 million, $12.4 million was allocated to the M923 product license together with the related research and development services, $12.4 million was allocated to each of the three additional product licenses with the related research and development services, $11.3 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 $137,000 was allocated to the joint steering committee unit of accounting.

Baxter's termination of M834 and the lapsing of Baxter's right to select additional products in February 2015 will reduce the number of deliverables from five to two and will decrease the expected consideration from $61.0 million to $40.0 million. 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. The Company will recognize the resulting change in revenue as a result of the decrease in deliverables and expected consideration on a prospective basis beginning in February 2015.

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 the second quarter of 2013, the Company commenced billing to Baxter external development costs for reimbursable activities related to M923. Beginning in the second half of 2013, the Company commenced billing to Baxter FTE fees related to M923. See tables above for research and development revenue earned by the Company under the Baxter Agreement. As of December 31, 2014, $31.0 million of revenue was deferred under this agreement, of which $5.5 million was included in current liabilities and $25.5 million was included in non-current liabilities in the consolidated balance sheet.

The Company has concluded that the M923 technical development milestones and the IND milestones pursuant to the Baxter 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.

Massachusetts Institute of Technology

The Company has an agreement dated November 1, 2002 with the Massachusetts Institute of Technology, or M.I.T., granting the Company various exclusive and non-exclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to:

- methods and technologies for characterizing polysaccharides;
- certain heparins, heparinases and other enzymes; and
- carbohydrate synthesis methods.

In exchange for the licenses granted in the agreement, the Company has paid M.I.T. license maintenance fees, royalties on certain products and services covered by the licenses and sold by the Company or its affiliates or sublicensees, a percentage of certain other income received by the Company from corporate partners and sublicensees, and certain patent prosecution and maintenance costs.

The following table summarizes the license maintenance fees and royalties paid to M.I.T. and recorded in the years ended December 31, 2014, 2013 and 2012 (in thousands):

	2014	2013	2012
License maintenance fees	$ 82	$ 82	$ 183
Royalties	317	252	1,013
Total	$ 399	$ 334	$ 1,196

The annual license maintenance obligations, which extend through the life of the patents, are approximately $0.1 million per year. The annual payments may be applied towards royalties payable to M.I.T. for that year for product sales, sublicensing of the patent rights or joint development revenue. The Company applied the annual license payments against cumulative royalties due to M.I.T. on sales of Enoxaparin Sodium Injection for the years ended December 31, 2014, 2013 and 2012.

The Company is obligated to indemnify M.I.T. and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements, unless the losses result from the indemnified parties' gross negligence or willful misconduct.

The agreement expires upon the expiration or abandonment of all patents that issue and are licensed to the Company by M.I.T. under such agreement. The issued patents include over 40 United States patents and foreign counterparts of some of those. Any such patent will have a term of 20 years from the filing date of the underlying application. M.I.T. may terminate the agreement immediately if the Company ceases to carry on its business, if any nonpayment by the Company is not cured within 60 days of written notice or the Company commits a material breach that is not cured within 90 days of written notice. The Company may terminate the agreement for any reason upon six months' notice to M.I.T., and it can separately terminate the license under a certain subset of patent rights upon three months' notice.

The Company granted Sandoz a sublicense under the agreement to certain of the patents and patent applications licensed to the Company. If M.I.T. converts the Company's exclusive licenses under this agreement to non-exclusive licenses due to the Company's failure to meet diligence obligations, or if M.I.T. terminates this agreement, M.I.T. will honor the exclusive nature of the sublicense the Company granted to Sandoz so long as Sandoz continues to fulfill its obligations to the Company under

the collaboration and license agreement the Company entered into with Sandoz. If the Company's agreement with M.I.T. is terminated, Sandoz agrees to assume the Company's rights and obligations to M.I.T.

10. Preferred and Common 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, 2014 and 2013, 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.

11. Share-Based Payments

Incentive Award Plans

In March 2013, the Company's Board of Directors adopted the 2013 Incentive Award Plan, or the 2013 Plan. The 2013 Plan 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 will be 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 will be 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. Restricted stock awards generally vest ratably over four years. Non-statutory stock options granted have varying vesting schedules. Incentive and non-statutory stock options generally expire ten years after the date of grant. Restricted stock awards are granted only to employees of the Company.

Under the 2013 Plan, the aggregate number of shares reserved for issuance is equal to the sum of: (a) 3,300,000 shares reserved for issuance under the 2013 Plan, plus (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 5,386,094 shares), plus

(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 1,137,394 shares). On April 14, 2014, the compensation committee of the board of directors approved an amendment and restatement of the 2013 Plan to increase the shares of common stock available for grant under the 2013 Plan by 1,800,000 shares. The amended and restated 2013 Plan became effective on June 11, 2014, the date the Company received stockholder approval. At December 31, 2014, 3,409,275 shares were available for issuance under the 2013 Plan.

Each share issued in connection with an award granted under the 2013 Plan, other than stock options and stock appreciation rights, will be counted against the 2013 Plan's share reserve as 1.35 shares for every one share issued in connection with such award, while each share issued in connection with an award of stock options or stock appreciation rights will count against the share reserve as one share for every one share granted.

The following table is a roll-forward of shares available for issuance under the 2013 Plan from June 11, 2013 through the year ended December 31, 2014 (in thousands):

	Shares Available for Issuance
Shares reserved for issuance at June 11, 2013	3,300
Add: June 2014 stockholder-approved increase in share pool	1,800
Stock options and restricted stock awards forfeited or expired under prior plans	223
Stock options and awards forfeited under 2013 Plan	114
Less: Stock options and awards granted under 2013 Plan	(2,028)
Shares reserved for issuance at December 31, 2014	3,409

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, 2014, 2013 and 2012 (in millions):

	2014	2013	2012
Outstanding employee and non-employee stock option grants	$ 9.7	$ 8.1	$ 7.4
Outstanding restricted stock awards	3.5	4.3	6.0
Employee stock purchase plan	0.4	0.4	0.3
Total compensation cost	$ 13.6	$ 12.8	$ 13.7

During the year ended December 31, 2014, the Company granted 1,399,172 stock options, of which 1,164,922 were granted in connection with annual merit awards, 142,000 were granted to the Company's board of directors, and 92,250 were 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		
	2014	2013	2012	2014	2013	2012
Expected volatility	66%	63%	66%	63%	64%	66%
Expected dividends	—	—	—	—	—	—
Expected life (years)	6.1	6.0	6.3	0.5	0.5	0.5
Risk-free interest rate	2.2%	1.5%	1.3%	0.1%	0.1%	0.1%

The following table presents stock option activity of the Company's 2013 Plan and prior stock plans for the year ended December 31, 2014:

	Number of Stock Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2014	6,239	$ 13.67		
Granted	1,399	17.14		
Exercised	(232)	9.46		
Forfeited	(222)	15.33		
Expired	(74)	14.77		
Outstanding at December 31, 2014	7,110	$ 14.43	5.79	$ 2,934
Exercisable at December 31, 2014	5,099	$ 14.00	4.74	$ 2,872
Vested or expected to vest at December 31, 2014	6,915	$ 14.38	5.70	$ 2,923

The weighted average grant date fair value of option awards granted during 2014, 2013 and 2012 was $10.51, $7.62 and $9.16 per option, respectively. The total intrinsic value of options exercised during 2014, 2013 and 2012 was $1.3 million, $2.7 million and $1.6 million, respectively. At December 31, 2014, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $15.6 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 2014, 2013 and 2012 was $10.1 million, $8.3 million and $7.4 million, respectively.

Cash received from option exercises for 2014, 2013 and 2012 was $2.2 million, $4.2 million and $1.5 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, 2014, the Company awarded 227,394 shares of time-based restricted common stock to its officers in connection with its annual merit grant. The time-based restricted common stock fully vests over the four years following 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 vests as to 50% of the shares upon FDA approval in the United States for M356, the Company's second major generic program, provided that approval occurs on or before March 28, 2015. The remaining 50% of the awards vest on the one-year anniversary of approval, as long as approval occurs on or before March 28, 2015 and the employment relationship exists on the

anniversary date. Each quarter the Company evaluates the probability of approval being obtained on or before March 28, 2015 and its estimate of the implicit service period over which the fair value of the awards will be recognized and expensed. The Company determined that it was probable that the performance condition would be achieved and therefore is expensing the fair value of the shares over the implicit service period. During 2014, the Company revised its estimate of the implicit service period and the impact of this change in estimate on the Company's net loss and net loss per share for the year ended December 31, 2014 was immaterial.

The Company recorded share-based compensation expense related to nonvested, outstanding restricted stock awards, including the performance-based shares, because the Company determined that it was probable the performance condition would be achieved, of $3.5 million, $4.3 million and $6.0 million for the years ended December 31, 2014, 2013 and 2012, respectively. Through December 31, 2014, the Company recorded cumulative share-based compensation of $10.5 million related to awards with performance conditions and it would need to reverse this expense if FDA approval is not attained on or before March 28, 2015. As of December 31, 2014, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $5.9 million, which is expected to be recognized over the weighted average remaining requisite service period of 1.3 years.

A summary of the status of nonvested shares of restricted stock as of December 31, 2014 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, 2014	1,134	$ 14.41
Granted	227	17.96
Vested	(145)	13.76
Cancelled	(42)	15.27
Nonvested at December 31, 2014	1,174	$ 15.15

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of December 31, 2014 are summarized below (in thousands):

Vesting Schedule	Nonvested Shares
Time-based	379
Performance-based	795
Nonvested at December 31, 2014	1,174

The total fair value of shares of restricted stock vested during 2014, 2013 and 2012 was $2.0 million, $2.0 million and $1.8 million, respectively.

Employee Stock Purchase Plan

In 2004, the Company's Board of Directors adopted the 2004 Employee Stock Purchase Plan, or ESPP. Since adoption of the ESPP through February 2014, an aggregate of 524,652 shares of common stock have been reserved for issuance under the ESPP. In March 2014, the board of directors approved the amendment and restatement of the ESPP to increase the shares of common stock available for grant under the ESPP by 500,000 shares. The amended and restated ESPP became effective on June 11, 2014, the date the Company received approval by its stockholders.

Under the ESPP, participating employees purchase common stock through payroll deductions. An employee may withdraw from an offering before the purchase date and obtain a refund of the amounts withheld through payroll deductions. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on the first business day and the last business day of the relevant plan period. The ESPP periods begin on February 1 and August 1 of each year. The Company issued 98,910 shares of common stock to employees under the ESPP during the year ended December 31, 2014. As of December 31, 2014, 527,968 shares of common stock have been issued to the Company's employees under the ESPP, and 496,684 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, 2014, subscriptions were outstanding for an estimated 68,657 shares at a fair value of approximately $3.43 per share. The weighted average grant date fair value of the offerings during 2014, 2013 and 2012 was $4.51, $4.73 and $5.17 per share, respectively. Cash received from the ESPP for 2014, 2013 and 2012 was $1.1 million, $0.9 million and $0.7 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, performance-based restricted common stock awards which vest based upon U.S. Food and Drug Administration, or FDA, approval for M356 in the United States were excluded from diluted shares outstanding as the vesting condition had not been met as of December 31, 2014.

The following table presents anti-dilutive shares for the years ended December 31, 2014, 2013 and 2012 (in thousands):

	2014	2013	2012
Weighted-average anti-dilutive shares related to:			
Outstanding stock options	5,941	4,492	3,815
Restricted stock awards	847	929	1,075

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, 2014 and 2013 are as follows, in thousands:

	2014	2013
Deferred tax assets:		
Federal and state net operating losses	$ 80,549	$ 50,414
Research credits	18,773	10,466
Deferred compensation	14,391	12,708
Deferred revenue	12,176	10,887
Accrued expenses	2,851	2,890
Intangibles	3,441	2,310
Depreciation	838	819
Unrealized loss on marketable securities	6	—
Total deferred tax assets	133,025	90,494
Deferred tax liabilities:		
Unrealized gain on marketable securities	—	(9)
Total deferred tax liabilities	—	(9)
Valuation allowance	(133,025)	(90,485)
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, 2014, 2013 and 2012 is as follows (in thousands):

	2014	2013	2012
Benefit at federal statutory tax rate	$ (33,521)	$ (36,856)	$ (19,931)
State taxes, net of federal benefit	(5,206)	(5,724)	(3,095)
Share-based compensation	2,411	2,106	2,655
Tax credits	(5,529)	(2,404)	—
Other	23	15	14
Change in valuation allowance	41,822	42,863	20,357
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 $42.5 million for the year ended December 31, 2014 due primarily to the current period net loss.

At December 31, 2014, the Company had federal and state net operating loss carryforwards of $221.8 million and $197.3 million, respectively, available to reduce future taxable income that will expire at various dates through 2034. Of this amount, approximately $13.4 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, 2014, the Company had federal and state research and development and other credit carryforwards, including the orphan drug credit, of $16.9 million and $8.6 million, respectively, available to reduce future tax liabilities that expire at various dates through 2034. 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, 2014 and 2013 is as follows (in thousands):

	2014	2013
Balance, beginning of year	$ 4,465	$ 2,897
Additions for tax positions related to the current year	940	1,568
Reductions of tax positions of prior years	(1,341)	—
Balance, end of year	$ 4,064	$ 4,465

As of December 31, 2014 and 2013, the Company had $4.1 million and $4.5 million of gross unrecognized tax benefits, respectively, of which $3.9 million and $4.3 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 2011, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2011. As of December 31, 2014, the Company's U.S. federal tax return for 2012 is under examination by the Internal Revenue Service.

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 in both 2013 and 2014, it recognized one-fifth of the $1.1 million job creation tax award, or $0.2 million, as other income in each of the years ended December 31, 2014, 2013 and 2012. 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 $16.3 million, $12.8 million and $10.0 million for the years ended December 31, 2014, 2013 and 2012, 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, ending April 2015. 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 through April 2018, or such other earlier date as provided in accordance with the West Kendall Sublease. During the extension term, which will commence on May 1, 2015, annual rental payments will be 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.

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.

Total operating lease commitments as of December 31, 2014 are as follows (in thousands):

	Operating Leases
2015	$ 11,177
2016	9,189
2017	4,924
2018	1,608
2019 and beyond	—
Total future minimum lease payments	$ 26,898

License Agreements

In connection with the research university license arrangement discussed in Note 9, the Company has certain annual fixed obligations to pay fees for the technology licensed. The annual financial obligations, which extend through the life of the patents, are approximately $0.1 million per year. The Company may terminate the agreement at any time without further annual obligations. Annual payments may be applied towards royalties payable to the licensor for that year for product sales, sublicensing of the patent rights or joint development revenue.

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.

On August 28, 2008, 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 Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for a 20 mg/mL formulation of M356. The suit alleged infringement related to four of the seven Orange Book-listed patents for Copaxone and sought declaratory and injunctive relief that would prohibit the launch of the Company's product until the last to expire of these patents. The Orange Book is a publication of the FDA that identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act and includes patents that are purported by the drug application owner to protect each drug. If there is a patent listed for the branded drug in the Orange Book at the time of submission of an ANDA, or at any time before an ANDA is approved, a generic manufacturer's ANDA must include one of four types of patent certification with respect to each listed patent. See Part I, Item 1. " *Business—Regulatory and Legal Matters* " in this Annual Report on Form 10-K. The Company and Sandoz asserted various defenses and filed counterclaims for declaratory judgments to have all seven of the Orange Book-listed patents, as well as two additional patents, in the same patent family adjudicated in that lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book-listed patents for Copaxone, and in October 2010, the Court consolidated the Mylan case with the case against the Company and Sandoz. A trial on the issue of inequitable conduct occurred in July 2011 and the trial on the remaining issues occurred in September 2011 in the consolidated case. In June 2012, the Court issued its opinion and found all of the claims in the patents to be valid, enforceable and infringed. In July 2012, the Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. In July 2012, the Company appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in July 2013, the CAFC issued a written opinion invalidating several of the nine patents, including one non Orange Book-listed patent which is set to expire in September 2015. The other patents expired on May 24, 2014. The CAFC remanded the case to the District Court to modify the injunction in light of the CAFC decision. In September 2013, Teva filed a petition for rehearing of the CAFC decision, and in October 2013 the CAFC denied the petition. Teva filed a petition for review by the Supreme Court of the United States in January 2014, and in March 2014 the Supreme Court granted certiorari in the case in order to review the appropriate standard for deference to district court findings in claim construction. Briefing was completed in September 2014, and oral argument was held in October 2014.

On January 20, 2015, the Supreme Court vacated the 2013 decision of the CAFC and remanded the case to the CAFC for additional findings to determine the validity of the relevant patent claims that had previously been determined to be invalid. In February 2015, the CAFC ordered the parties to file briefs by March 2, 2015. During the pendency of this litigation any launch of M356 would be a launch at risk of infringement.

On September 10, 2014, Teva and 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 a 40 mg/mL formulation of M356. The suit alleges infringement related to two Orange Book-listed patents for 40 mg/mL Copaxone, 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. The Company and Sandoz have asserted various defenses and filed counterclaims for declaratory judgments of non-infringement, invalidity and unenforceability of both patents.

On September 21, 2011, the Company and Sandoz sued Amphastar, Actavis and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) 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, Actavis and International Medical Systems, Ltd. 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, Actavis and International Medical Systems, Ltd. 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, Actavis and International Medical Systems, Ltd. appealed the decision to the CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding 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 January 2013, Amphastar and Actavis filed a motion for summary judgment in the District Court following the decision from the CAFC and in July 2013, the District Court granted the motion 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. The Company opposed this motion and the CAFC denied the motion in May 2014. The CAFC set a briefing schedule which ended in November 2014. The Company expects the CAFC will hold a hearing on its appeal during the first half of 2015, the Company expects a decision in 2015. The collateral for the security bond posted in the litigation remains outstanding. In the event that the Company is not successful in any appeal, and Amphastar and Actavis are 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.

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, $0.8 million and $0.7 million of such match expense in the years ended December 31, 2014, 2013 and 2012, respectively.

16. At-The-Market Offering

In May 2014, the Company entered into an At-The-Market Equity Offering Sales Agreement, or the Sales Agreement, with Stifel, Nicolaus & Company, Incorporated, or 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 offering is being conducted by the Company pursuant to a shelf registration statement previously filed with the Securities and Exchange Commission. The proceeds from this facility will be used to advance our development pipeline and for general corporate purposes, including working capital. As of December 31, 2014, the Company sold approximately 1.7 million shares of common stock pursuant to the Sales Agreement, of which 1.6 million were issued and outstanding as of the year end. In connection with the ATM financing, the Company raised aggregate proceeds of $19.4 million, of which $18.3 million was received by year end and is included in its consolidated statement of comprehensive loss.

The Company sold an additional 1.4 million shares of common stock pursuant to the Sales Agreement subsequent to year-end through February 26, 2015 resulting in aggregate proceeds of approximately $18.8 million.

17. Selected Quarterly Financial Data (Unaudited)

	Quarter Ended			
(in thousands, except per share data)	March 31	June 30	September 30	December 31
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
2013				
Product revenue	$ 5,396	$ 1,628	$ 4,774	$ 4,903
Research and development revenue	$ 2,207	$ 2,733	$ 5,977	$ 7,847
Total collaboration revenue	$ 7,603	$ 4,361	$ 10,751	$ 12,750
Net loss	$ (24,116)	$ (28,848)	$ (25,382)	$ (30,062)
Comprehensive loss	$ (24,181)	$ (28,872)	$ (25,284)	$ (30,157)
Basic and diluted net loss per common share	$ (0.48)	$ (0.57)	$ (0.50)	$ (0.59)
Shares used in computing basic and diluted net loss per common share	50,635	50,746	51,055	51,185

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

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of December 31, 2014. 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, 2014, 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, 2014, 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, 2014, 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, 2014, 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, 2014, 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, 2014 and 2013, 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, 2014 of Momenta Pharmaceuticals, Inc. and our report dated February 27, 2015 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 27, 2015

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended December 31, 2014 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—Section 16(a) Beneficial Ownership Reporting Compliance" and "Momenta's Corporate Governance—Board Committees" in our definitive proxy statement for our 2015 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 2015 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 and Related Stockholder Matters" in our definitive proxy statement for our 2015 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 2015 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 2015 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 2015 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 27, 2015

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 27, 2015
/s/ RICHARD P. SHEA Richard P. Shea	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2015
/s/ JAMES SULAT James Sulat	Chairman of the Board of Directors	February 27, 2015
/s/ JOHN K. CLARKE John K. Clarke	Director	February 27, 2015
/s/ BRUCE DOWNEY Bruce Downey	Director	February 27, 2015
/s/ MARSHA H. FANUCCI Marsha H. Fanucci	Director	February 27, 2015
/s/ THOMAS KOESTLER, Ph.D. Thomas Koestler, Ph.D.	Director	February 27, 2015
/s/ BENNETT M. SHAPIRO, M.D. Bennett M. Shapiro, M.D.,	Director	February 27, 2015
/s/ ELIZABETH STONER, M.D. Elizabeth Stoner, M.D.,	Director	February 27, 2015

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
10.2†	Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant (the "November 1, 2002 M.I.T. License"); First Amendment to the November 1, 2002 M.I.T. License, dated November 15, 2002, by and between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated September 12, 2003, between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated October 22, 2003, between the Massachusetts Institute of Technology and the Registrant; Second Amendment to the November 1, 2002 M.I.T. License, dated November 19, 2003, by and between the Massachusetts Institute of Technology and the Registrant; Third Amendment to the November 1, 2002 M.I.T. License, dated April 2, 2004, by and between the Massachusetts Institute of Technology and the Registrant	8-K	10.1	8/15/2006	000-50797
10.2.1†	Letter Agreement Regarding November 1, 2002 M.I.T. License, dated August 4, 2006, between the	8-K	10.1	8/15/2006	000-50797

10.2.2†	Massachusetts Institute of Technology and the Registrant Letter Agreement Regarding November 1, 2002 M.I.T. License, dated October 18, 2006, between the Massachusetts Institute of Technology and the Registrant	10-Q	10.6	11/8/2006	000-50797

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.2.3†	Fourth Amendment to the November 1, 2002 M.I.T. License, dated July 17, 2004, by and between the Massachusetts Institute of Technology and the Registrant	10-Q	10.3	8/16/2004	000-50797
10.2.4†	Fifth Amendment to the November 1, 2002 M.I.T. License, dated August 5, 2006, by and between the Massachusetts Institute of Technology and the Registrant	10-Q	10.5	11/8/2006	000-50797
10.2.5	Sixth Amendment to the November 1, 2002 M.I.T. License, dated January 10, 2007, by and between the Massachusetts Institute of Technology and the Registrant	10-K	10.8	3/15/2007	000-50797
10.2.6	Letter Agreement Regarding the November 1, 2002 M.I.T. License, dated June 12, 2007, between the Massachusetts Institute of Technology and the Registrant	10-Q	10.2	8/9/2007	000-50797
10.2.7	Seventh Amendment to the Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant dated June 1, 2009	10-Q	10.1	8/6/2009	000-50797
10.2.8†	Letter Agreement, dated December 22, 2010, by and between the Registrant and the Massachusetts Institute of Technology	8-K	10.1	12/23/2010	000-50797
10.3	Letter Agreement dated January 29, 2007 between Sandoz AG and the Registrant	10-K	10.16	3/15/2007	000-50797
10.4	Letter Agreement dated February 1, 2007 between Sandoz AG and the Registrant	10-Q	10.2	5/10/2007	000-50797
10.5†	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
10.5.1	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
10.5.2†	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
10.5.3	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
10.6	Letter Agreement dated November 8, 2011 by and between the Registrant, Sandoz AG and Sandoz Inc.	10-K	10.20	2/28/2012	000-50797
10.7†	Development, License and Option Agreement by and between the	10-K	10.21	2/28/2012	000-50797

Registrant and Baxter
International Inc., Baxter Healthcare
Corporation and Baxter
Healthcare SA dated December 22,
2011

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to Exhibit No.	Filing Date with SEC	SEC File Number
	Material Contracts—Management Contracts and Compensation Plans				
10.8#	Amended and Restated 2002 Stock Incentive Plan	10-K	10.17	3/15/2007	000-50797
10.9#	2004 Stock Incentive Plan, as amended	10-K	10.18	3/15/2007	000-50797
10.10#	Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.1	8/16/2004	000-50797
10.11#	Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.2	8/16/2004	000-50797
10.12#	Form of Restricted Stock Agreement Under 2004 Stock Incentive Plan	8-K	10.2	2/28/2008	000-50797
10.13#	2004 Employee Stock Purchase Plan (as amended and restated)	8-K	10.2	6/17/2014	000-50797
10.14#	Non-Employee Director Compensation Summary	10-Q	10.3	8/5/2011	000-50797
10.15#	Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.15.1#	Amendment dated December 16, 2010 to the Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-K	10.28	3/10/2011	000-50797
10.16#	Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.8	11/8/2006	000-50797
10.17#	Nonstatutory Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.9	11/8/2006	000-50797
10.18#	Incentive Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.10	11/8/2006	000-50797
10.19#	Restricted Stock Agreement, dated December 15, 2006, between John E. Bishop and the Registrant	10-K	10.56	3/15/2007	000-50797
10.20#	Restricted Stock Agreement, dated December 14, 2007, between John E. Bishop and the Registrant	10-K	10.35	3/10/2008	000-50797
10.21#	Restricted Stock Agreement, dated August 15, 2007, between Richard P. Shea and the Registrant	10-Q	10.1	11/08/2007	000-50797
10.22#	Form of Employment Agreement for executive officers	10-Q	10.3	5/9/2008	000-50797
10.23#	Second Amended and Restated Employment Agreement, dated April 28, 2008, by the Registrant and Ganesh Venkataraman	10-Q	10.4	5/9/2008	000-50797
10.24#	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
10.25#	Form of Amendment to the Employment Agreement for executive officers dated December 15, 2010	10-K	10.39	3/10/2011	000-50797

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.26#	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
10.27#	Form of Restricted Stock Agreement	8-K	10.1	4/1/2011	000-50797
10.28#	Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan (as amended and restated)	8-K	10.1	6/17/2014	000-50797
10.29#	Form of Stock Option Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan	8-K	10.1	6/13/2013	000-50797
10.30#	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				
10.31†	Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.9	11/12/2004	000-50797
10.31.1	First Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004), dated September 7, 2005, between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.3	11/14/2005	000-50797
10.31.2	Second Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of November 21, 2005, between Vertex Pharmaceuticals Incorporated and the Registrant	10-K	10.47	3/16/2006	000-50797
10.31.3	Third Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of January 27, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant	10-K	10.48	3/16/2006	000-50797
10.31.4	Letter Agreement (regarding Sublease Agreement, dated September 14, 2004, as amended), dated June 29, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.1	8/9/2006	000-50797
10.31.5	Fourth Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of July 14, 2014, between Vertex Pharmaceuticals Incorporated and the Registrant	8-K	10.1	7/18/2014	000-50797
10.32	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
10.32.1	First Amendment dated March 21, 2013 to the Sublease Agreement dated February 5, 2013 by and	10-Q	10.2	5/10/2013	000-50797

between BMR-Rogers Street LLC
and the Registrant

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.32.2	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
	Material Contracts—Stock Purchase Agreement				
10.33	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				
10.34	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
10.34.1	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
10.34.2	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				
10.35	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
	Additional Exhibits				
*21	List of Subsidiaries				
*23.1	Consent of Independent Registered Public Accounting Firm				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
**32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				
*101.INS	XBRL Instance Document.				
*101.SCH	XBRL Taxonomy Extension Schema Document.				

*101.CAL	XBRL Taxonomy 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.

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
*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, 2014, filed with the SEC on February 27, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Comprehensive Loss for the years ended December 31, 2014, 2013, and 2012, (ii) the Consolidated Balance Sheets as of December 31, 2014 and 2013, (iii) the Consolidated Statements of Cash Flows for the years ended December 31, 2014, 2013, and 2012, (iv) the Consolidated Statements of Stockholders' Equity for the years ended December 31, 2014, 2013, and 2012 and (v) Notes to Consolidated Financial Statements.

EXHIBIT 21

SUBSIDIARIES OF MOMENTA PHARMACEUTICALS, INC.

Name of Subsidiary	Jurisdiction of Organization
Momenta Pharmaceuticals Securities Corporation	Massachusetts

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SUBSIDIARIES OF MOMENTA PHARMACEUTICALS, INC.

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. 333-197582, 333-190394, 333-179760, 333-172155, 333-164892, 333-157275, 333-149253, 333-140760 and 333-117173) of Momenta Pharmaceuticals, Inc. and where applicable, in the related Prospectuses of our reports dated February 27, 2015, 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, 2014.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 27, 2015

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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 27, 2015

/s/ CRAIG A. WHEELER

Craig A. Wheeler
President and Chief Executive Officer

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Exhibit 31.1

CERTIFICATIONS

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 27, 2015

/s/ RICHARD P. SHEA

Richard P. Shea
Senior Vice President and Chief Financial Officer

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Exhibit 31.2

CERTIFICATIONS

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, 2014 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 27, 2015

/s/ CRAIG A. WHEELER

Craig A. Wheeler
President and Chief Executive Officer

Dated: February 27, 2015

/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