# 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, 2013**

**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 28, 2013, based on $15.06 per share, the last reported sale price of Common Stock on the Nasdaq Global Market on that date, was $759,224,102.

As of February 15, 2014, the registrant had 52,475,911 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 the 2014 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

*Statements contained or incorporated by reference in this Annual Report on Form 10-K that are not based on 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 forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, general and administrative expenses, research and development expenses, current and future development and manufacturing efforts, regulatory filings, clinical trial results and the sufficiency of our cash for future operations. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "hope," "target," "project," "goals," "potential," "predict," "might," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms.*

*We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below under Part I Item 1A "Risk Factors." We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

## PART I

### Item 1. BUSINESS

#### The Company

We are a biotechnology company operating in three product areas: Complex Generics, Biosimilars and Novel Drugs. Our approach 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 based on this knowledge, analyze sets of biological data to evaluate the biological function of our products, and develop manufacturing processes that enable our products to be reliably produced. Our first product, developed in collaboration with Sandoz, Enoxaparin Sodium Injection, a generic version of Lovenox®, was approved in July of 2010, validating the commercial value of our platform. In the period from commercial launch through September 2011, we capitalized on the advantage of having the only generic version of Lovenox in the marketplace and recognized over $340 million in revenue from this product.

#### Our Approach

The core objective of our complex systems analysis platform is to resolve the complexity of molecular structures and related biologic systems. For the complex systems we seek to understand, we first map the key measurements needed to provide comprehensive data on the system. We then develop a set of analytic tools and methods that include a combination of standard analytics, modified analytic approaches and custom developed analytics and methods. The modified and custom analytics may be protected by trade secrets or patents. The analytic set we use for a development program is designed to provide comprehensive data on the complex molecular mixture and target biology, including providing multiple related and complementary, or orthogonal, measures of the system. We also may use computer software to mine and synthesize the data to yield insights that advance our development programs across all three product areas. As we expand our infrastructure, intellectual property and knowledge of complex biologies, we accrue advantages as well. For example, the process development and manufacturing expertise developed from our complex generic and biosimilars efforts can be directly

used to advance our novel drug candidates. The investments in biocharacterization made for our biosimilars program provide a core of models and biologic data sets that can form the basis of inquiries in our novel drug research. And the analytic tools and methods and biologic models we develop help build a substantial toolset that can be used across our programs.

**Complex Generics**

In our Complex Generics product area, we develop generic versions of complex drugs that were approved by the United States Food and Drug Administration, or FDA, under New Drug Applications, or NDAs. Most drugs approved as NDAs are simple small molecules that are easy to duplicate. However, products such as Lovenox and Copaxone®, the generic version of which is our second complex generic product candidate, are complex molecular mixtures that are difficult to analyze and therefore difficult to reproduce as generics.

We use our complex systems analysis platform to define the detailed structures present in these complex drugs. Once the precise structures are identified, or characterized, this structural characterization of the brand product is used to guide the development of a precise manufacturing process to produce a generic version. Finally, to demonstrate that the biological function of our generic replicates that of the brand, 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.

**Biosimilars**

In our Biosimilars product area, we are seeking to develop biosimilar versions of biologic medicines that were approved by the FDA under Biologics License Applications, or BLAs. Biologics are also complex mixtures, and we unlock their structural subtleties using an approach that is similar to the one we use in the development of our complex generics. A key difference, however, is that biologic drugs are manufactured in living cells, which dramatically increases the complexity of their manufacturing process.

For Biosimilars, we apply our complex systems analysis platform in two ways. First, we seek to better understand the complex systems within cells that are involved in the assembly of proteins. This knowledge enables us to select the appropriate cell line and to manipulate the cell's outputs using novel control strategies during the manufacturing with the goal of producing a biologic with structural similarity to the brand. Nevertheless, because of the complexity and variability of biologic manufacturing systems, it is important to evaluate whether any small differences between the biosimilar and the brand would be related to potential clinical differences. To minimize this residual uncertainty, we 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 brand product and our product. We believe that our complex systems analysis approaches, including these characterization methods, can significantly reduce residual uncertainty and may enable a relative reduction or even elimination of certain clinical trial requirements.

**Novel Drugs**

Momenta was originally founded to develop novel drugs, and this remains a key long term goal for us today. We believe that applying our complex systems analysis platform to the discovery and development of novel medicines can enhance our probability of success in a number of ways. As with our complex generics and biosimilars, our platform 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.

In our research efforts, we use computer algorithms to analyze related sets of biologic data to provide deeper insight into the complexities inherent in human biology. By embracing this complexity

early in the discovery process, our goal is 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 preclinical 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.

We are using these approaches with M402, our oncology product candidate presently in a Phase 1/2 clinical study. We are also applying our complex systems analysis platform to identify potential improvements we can design into presently marketed complex mixture drugs. By evaluating their interaction with biologic systems, we can obtain an enhanced understanding of their function to identify biological activities we can exploit. This is the approach behind our research efforts to exploit the sialylation of intravenous immunoglobulin, or IVIg, and our program to develop a recombinant Fc version of IVIg.

**Commercial, Development and Research Programs**

| Product Area | Program | Discovery | Development | Market |
|---|---|---|---|---|
| Complex Generics | Enoxaparin Sodium Injection (Polysaccharide) | | | |
| | M356 (Peptide) | | | |
| Biosimilars | M923 (Protein) | | | |
| | M834 (Protein) | | | |
| | M511 (Protein) | | | |
| Novel Drugs | M402 (Polysaccharide) | | | |
| | Discovery Program | | | |

**Our Product Areas**

**Complex Generics**

***Enoxaparin Sodium Injection—Generic Lovenox®***

Enoxaparin Sodium Injection, our first product to receive marketing approval under an ANDA, is a generic version of Lovenox. Lovenox is a complex drug consisting of a mixture of polysaccharide chains and 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 distributed worldwide by Sanofi-Aventis U.S. LLC, or Sanofi-Aventis, and is also known outside the United States as Clexane® and Klexane®.

*Description of Our Program*

Lovenox is a heterogeneous mixture of complex polysaccharide chains that, in our view, prior to the application of our technology, had not been adequately analyzed. The length and sequence of the polysaccharide chains vary, resulting in a diversity of chemical structures in the mixture. Our technology

and analytical approach allowed us to thoroughly characterize Lovenox which enabled FDA approval of the ANDA.

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.

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 expanded the geographic markets for Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union.

*Regulatory Matters*

Sandoz submitted ANDAs in its name to the FDA for Enoxaparin Sodium Injection in syringe and vial forms, seeking approval to market Enoxaparin Sodium Injection in the United States. The ANDA for the syringe form of Enoxaparin Sodium Injection was approved in July 2010, making it the first ANDA for a generic Lovenox to be approved by FDA. The ANDA for the vial form of Enoxaparin Sodium Injection was approved in December 2011.

*Commercial Market*

Due to additional competition in the generic enoxaparin market, which has impacted pricing, the overall United States enoxaparin market size has declined. Sanofi reported $248 million (€187 million) and $410 million (€319 million) in sales of brand Lovenox in the United States in 2013 and 2012, respectively. Sandoz reported $213 million and $451 million in sales of Enoxaparin Sodium Injection in the United States in 2013 and 2012, respectively. Pursuant to the 2003 Sandoz Collaboration, Sandoz is responsible for commercialization and distribution of Enoxaparin Sodium Injection.

*Legal Matters*

In September 2011, we and Sandoz sued Amphastar Pharmaceuticals, Inc., or Amphastar, Watson Pharmaceuticals, Inc. (now Actavis, Inc., or 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 sodium 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 requiring 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 Court of Appeals for the Federal Circuit, or CAFC, and in January 2012, the CAFC stayed the preliminary injunction. Amphastar has filed motions to increase the amount of the security bond, which we and Sandoz have opposed. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding the case to the District Court, holding that Amphastar's use of our patented method for processing Enoxaparin Sodium Injection was protected by the "safe harbor" from patent infringement under federal patent law, 35 U.S.C. Section 271(e)(1).

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 December 2010, we sued Teva Pharmaceutical Industries Ltd., or Teva, in the United States District Court for the District of Massachusetts for infringement of two of our patents related to Enoxaparin Sodium Injection. In January 2013, Teva filed a motion for summary judgment in the District Court following the decision from the CAFC in the aforementioned case and in July, 2013, the District Court granted the motion for summary judgment. We have filed a notice of appeal of the decision to the CAFC.

***M356—Generic Copaxone® (glatiramer acetate injection)***

Our second complex generic product candidate, M356, is designed to be a generic version of Copaxone (glatiramer acetate injection), a complex drug consisting of a synthetic mixture of polypeptide chains. Copaxone 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.

*Description of Our Program*

Under the Second Sandoz Collaboration Agreement, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356, among other products. Given its structure as a complex mixture of polypeptide chains of various lengths and sequences, there are significant technical challenges involved in thoroughly characterizing Copaxone and in manufacturing an equivalent version. We believe our technology can be applied to characterize glatiramer acetate and to develop a generic product that has the same active ingredient as Copaxone. We are continuing to expand our portfolio of pending patent applications related to glatiramer acetate injection.

In connection with the 2006 Sandoz Collaboration, 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, 2013, Novartis AG owns approximately 9% of our outstanding common stock.

*Regulatory Matters*

In December 2007, Sandoz submitted to the FDA an ANDA seeking approval to market our joint product M356 in the United States containing a Paragraph IV certification. This is a certification by the ANDA applicant that the patent relating to the drug product that is the subject of the ANDA is invalid, unenforceable or will not be infringed. In July 2008, the FDA notified Sandoz that it had accepted the ANDA for review as of December 27, 2007. The Sandoz ANDA for M356 is currently under FDA review.

Since 2008, Teva has filed six Citizen Petitions with FDA requesting FDA deny approval of any ANDA filed for generic Copaxone. The FDA has denied the first four Citizen Petitions filed by Teva. We anticipate Teva will continue to engage in activities that seek to challenge the approval of our M356 ANDA.

*Potential Commercial Market*

In North America, Copaxone is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva. Teva reported worldwide sales of Copaxone of approximately $4.3 billion in 2013, with approximately 74%, or $3.2 billion, from the United States.

*Legal Matters*

Subsequent to FDA's acceptance of the ANDA for review, in August 2008, Teva and related entities and Yeda Research and Development Co., Ltd., filed suit against us and Sandoz in the United States Federal District Court in the Southern District of New York. The suit alleged infringement related to four of the seven Orange Book patents listed for Copaxone. 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 the present 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 patents listed 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. The Orange Book patents and one non-Orange book patent expire in May 2014 and one non-Orange Book patent expires in September 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35 U.S.C. Section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz or Mylan ANDA prior to the expiration of the Orange Book patents. In July 2012, we appealed the decision to the CAFC, and in July 2013, the CAFC issued a written opinion invalidating several of the patents, including the one patent set to expire in 2015. Several patents expiring in May 2014 remain in force. 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 in January 2014.

In December 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and us for patent infringement related to certain other non-Orange Book patents seeking declaratory and injunctive relief that would prohibit the launch of our product until the last to expire of these patents as well as damages in the event that Sandoz has launched the product. In January 2010, we and Sandoz filed a motion to dismiss this second suit on several grounds and in July 2013, the motion to dismiss the suit was granted.

***Biosimilars***

*Description of Our Program*

We are also applying our complex systems analysis platform to the development of biosimilar versions of marketed therapeutic proteins, with a goal of obtaining FDA designation as interchangeable. In March 2010, an abbreviated regulatory process was codified in Section 351(k) of the Patient Protection and Affordable Care Act of 2010. This new pathway opened the market for biosimilar and interchangeable versions of a broad array of biologic therapeutics, including antibodies, cytokines, fusion proteins, hormones and blood factors. By 2015, sales of biosimilars are expected to reach between $1.9 billion to $2.6 billion. In February 2012, FDA released three documents containing their preliminary guidelines for applications under the Section 351(k) pathway. These guidelines state that FDA will use a step-wise review that considers the totality-of-the-evidence in determining extent of the clinical development program. This approach puts a substantial emphasis on structural and functional characterization data in evaluating biosimilar products for approval. We believe that our strategy for the development of biosimilars aligns well with the framework that the FDA has outlined in the draft guidance documents.

Given the inadequacies of standard technology available at the time of original review and approval, many of these therapeutic proteins have not been thoroughly characterized. Most of these

products are complex glycoprotein mixtures, consisting of proteins that contain branched sugars that vary from molecule to molecule. These sugars can impart specific biological properties to the therapeutic protein and can often comprise a significant portion of the mass of the molecule. In addition to the structural characterization of several marketed therapeutic proteins, we are also advancing our structure-process capabilities as we further define the relationship between aspects of the manufacturing process and the structural composition of the final protein product. We believe our approach has the potential to drive regulatory advantages such as a reduction in the level of clinical data required for approval, or the achievement of a designation of interchangeability, which would allow our products to be directly substituted for brand products at the pharmacy.

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. Baxter is an established healthcare company with global product development, manufacturing and commercial capabilities. 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.

- M923, a biosimilar for a branded biologic indicated for certain autoimmune and inflammatory diseases, is our most advanced biosimilar. We are working toward progressing this program to the clinic in Europe, which is targeted for the second half of 2014.
- M834, a biosimilar for a branded biologic indicated for certain autoimmune and inflammatory diseases. We are working toward achievement of a pre-defined "minimum development criteria" license payment in 2014.

In July 2012, Baxter selected a third product for inclusion in the collaboration, a monoclonal antibody for oncology designated as M511. On December 19, 2013, Baxter terminated its option to license M511 under the Baxter Agreement following an internal portfolio review. We continue to collaborate with Baxter on M923 and M834 and evaluate additional products for development. We are continuing to develop M511 as part of our biosimilars program. Baxter has the right, until February 2015, to select up to three additional biosimilars to be included in the collaboration. We may also consent, at our option, to allow Baxter to name a replacement product for M511, if Baxter requests such replacement.

*Regulatory Matters*

Most protein drugs have been approved by the FDA under the BLA regulatory pathway. The BLA pathway was created to review and approve applications for biologic drugs that are typically produced from living systems. Until 2010, there was no abbreviated regulatory pathway for the approval of interchangeable or biosimilar versions of BLA-approved products in the United States; however, there have been guidelines for biosimilar products in the European Union for several years.

In March 2010, with the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCI, an abbreviated pathway for the approval of biosimilars and interchangeable biologics was created. The new abbreviated regulatory pathway established legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable," based on its similarity to an existing brand product.

Under the BPCI, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original brand product was approved under a BLA. There are many biologics at this time for which this 12-year period has expired or is nearing expiration. We believe that scientific progress in the analysis and characterization of complex mixture drugs is likely to play a significant role in FDA's approval of biosimilar (including interchangeable) biologics in the years to come.

In 2012, the FDA implemented its proposed biosimilar user fee program which includes a fee-based meeting process for consultation between applicants and the division of FDA responsible for reviewing 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 nonclinical and clinical requirements for a biosimilar or interchangeable biologic product.

The new law is complex and is in the initial stages of being interpreted and implemented by the FDA. As a result, we expect that its ultimate impact, implementation and meaning will be subject to uncertainty for years to come.

***Novel Drugs***

***Overview***

Our novel drugs program uses the established characterization and process engineering capabilities from our complex generics and biosimilars programs—with a focus on polysaccharides and therapeutic proteins.

***M402***

M402 is a novel oncology drug candidate engineered to have a broad range of effects on tumor cells. 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. M402, which is derived from unfractionated heparin, has been engineered to have significantly reduced anticoagulant activity while preserving the relevant antitumor properties of heparin.

Researchers have conducted a series of nonclinical experiments using different pancreatic cancer models to test the hypothesis that M402 can modulate tumor progression and metastasis and enhance the efficacy of gemcitabine, a first-line standard of care chemotherapy treatment for pancreatic cancer. The nonclinical results showed potent binding of M402 to multiple growth factors, adhesion molecules, and chemokines to inhibit tumor progression, metastasis, and angiogenesis. Additionally, the nonclinical data showed that M402 in combination with gemcitabine prolonged survival and substantially lowered the incidence of metastasis, suggesting that M402 has the potential to complement conventional chemotherapy. We believe that M402's mechanism of action, by binding to multiple heparin binding factors involved in tumor growth and metastasis, creates the potential for M402 to contribute to efficacy in a broad range of cancers.

In 2012, we initiated a Phase 1/2 proof-of-concept clinical study in patients with advanced metastatic pancreatic cancer. The trial consists of two parts and will evaluate the safety, potential efficacy, pharmacokinetics and pharmacodynamics of M402 in combination with nab-paclitaxel and gemcitabine. Part A is an open-label, multiple ascending dose escalation study. We have completed several cohorts in Part A of the trial. Dose escalation data from Part A are expected during the first half of 2014. Pending successful completion of this phase, we expect to initiate Part B of the trial, which will be a randomized, controlled study investigating the safety and antitumor activity of M402 administered in combination with nab-paclitaxel and gemcitabine, compared with nab-paclitaxel and gemcitabine alone.

***Discovery Research Program***

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 which may positively modulate multiple pathways in a disease.

IVIg, a mixture of human immunoglobulin G, or IgG, antibodies, is the last line of defense in many severe inflammatory diseases. IVIg is approved in several inflammatory disease indications including idiopathic thrombocytopenic purpura, Kawasaki disease, chronic inflammatory demyelinating polyneuropathy, and multifocal motor neuropathy. Currently, IVIg is manufactured from large pools of human plasma, resulting in a high cost supply chain with limited supply. IVIg is also approved to treat primary immunodeficiency for diseases such as AIDS. While not a focus of our research, this indication further limits available supply of IVIg. Increasing demand for IVIg products already exceeds available supply worldwide thus limiting broader clinical applications.

Our research program seeks to better understand the complex biology underlying the anti-inflammatory effects of IVIg and use this understanding to develop enhanced versions of IVIg or alternative recombinant molecules with improved efficacy. In 2013, we advanced our understanding of the biologic impact of sialylation, a method to add sialic acid to proteins, on the activity of IVIg as well as the behavior of recombinant molecules engineered from the Fc region of IgG. Through our testing in various models of inflammation, we have gained a deeper understanding of the basic biologic pathways by which these molecules mediate their therapeutic effects. We are turning our efforts to developing recombinant product candidates to take advantage of this understanding. This approach will give us an opportunity to more carefully design a product candidate to target the specific biologic effects we have observed as well as give us the opportunity to take advantage of a recombinantly produced product.

**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 2013 was $104.0 million, compared with $80.3 million in 2012 and $64.7 million in 2011.

**Collaborations, Licenses and Asset Purchases**

***Sandoz***

*2003 Sandoz Collaboration*

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. The profit-share or royalties Sandoz is obligated to pay us under the 2003 Sandoz Collaboration differ depending 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. 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 CAFC's granting a stay of the preliminary injunction previously issued by the United States District Court for the District of Massachusetts, 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*

Under the Second Sandoz Collaboration Agreement, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356, among other products, and expanded the geographic markets covered by the 2003 Sandoz Collaboration related to Enoxaparin Sodium Injection to include the European Union. In December 2008, we and Sandoz AG terminated the collaborative program with regard to one of the follow-on products, M249, primarily due to its commercial prospects. In December 2009, we and Sandoz AG terminated the collaborative program with regard to the other follow-on product, M178, and clarified the surviving rights of each of the parties following such termination. As a result, the Second Sandoz Collaboration Agreement now principally governs the M356 collaborative program and the expansion of the 2003 Sandoz Collaboration.

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 and costs will be borne by Sandoz AG worldwide as they are incurred for all products. 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 will be offset against the profit-sharing amounts in proportion to our profit sharing interest. The parties will share profits in varying proportions, depending on the product. We are entitled to a 50% share of the contractual profits from sales of M356. 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 the products under the collaboration, which include: a $10.0 million regulatory milestone payment related to the approval by the FDA of M356, and $153.0 million in sales-based and commercial milestone payments, of which up to $140.0 million (including the M356 regulatory milestone) are U.S.-based milestones. 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 terms of the Stock Purchase Agreement, we sold 4,708,679 shares of common stock to Novartis Pharma AG, an affiliate of Sandoz AG, at a per share price of $15.93 for an aggregate purchase price of $75.0 million. This resulted in a paid premium of $13.6 million as the closing price of our common stock on the NASDAQ Global Market was $13.05 on the date of the Stock Purchase Agreement.

Pursuant to the terms of 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 entered into the Baxter Agreement, which became effective in February 2012, following expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended.

Under the Baxter Agreement, we agreed to collaborate, on a world-wide basis, on the development and commercialization of two biosimilar products, M923 and M834, indicated for certain autoimmune and inflammatory diseases, or the initial products. In July 2012, Baxter selected a third biosimilar for inclusion in the collaboration known as M511, a monoclonal antibody for oncology, and we initiated development of this product. In December 2013, Baxter terminated its option to license M511 under the Baxter Agreement following an internal portfolio review. We are continuing to develop M511 as part of our internal biosimilars program.

The process for achieving milestones under the Baxter Agreement is as follows:

- Baxter selects an additional product to the collaboration and we initiate development.
- If we achieve pre-defined "minimum development" criteria related to the additional product, Baxter is given an option to exercise exclusive license rights.
- If Baxter exercises its exclusive license option to advance the additional product under the Baxter Agreement, we will earn a license payment.
- If we achieve pre-defined "technical development" criteria related to an initial product or additional product, we will earn a milestone payment.
- For an initial and additional product, if we either (a) submit an Investigational New Drug application, or IND, to the FDA or equivalent application in the European Union or (b) are not required to file an IND, either referred to as the "Transition Period," we will earn a milestone payment.
- Following the Transition Period, Baxter will assume responsibility for development of each biosimilar, and we have the potential to receive up to $250.0 million in regulatory milestone payments. These milestones are designed to reward the Company, on a sliding scale, for reducing the scope of the clinical activities required to develop each biosimilar.

Under the Baxter Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize designated products for all therapeutic indications. We have agreed to provide development and related services on a commercially reasonable basis through the Transition Period for each product, 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 any products covered by the Baxter Agreement. 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 products 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 have the option to participate, at our discretion, in a cost and profit share arrangement for the three additional products up to 30%. If the profit share is elected, the royalties payable would be reduced by up to nearly half. Absent a cost share arrangement, 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.

In addition, we have agreed, for a period commencing six months following the effective date and ending on the earlier of (i) three years from the effective date of the Baxter Agreement (subject to certain limited time extensions as provided in the Baxter Agreement) or (ii) the selection of the three additional products, to notify Baxter of bona fide offers from third parties to develop or commercialize a biosimilar that could be an additional product candidate. Following such notification, if Baxter does not select such proposed product or products for inclusion in the collaboration, we have the right to develop, manufacture, and commercialize such product or products on our own or with a third party. We also agreed to provide Baxter with a right of first negotiation with respect to collaborating in the development of a competing product 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. Following the third anniversary of the effective date of the Baxter Agreement (subject to certain limited time extensions, as provided for in the Baxter Agreement), we may develop, on our own or with a third party, any biosimilar products not named under the Baxter Agreement, subject to certain restrictions.

Under the terms of the Baxter Agreement, we received an initial cash payment of $33.0 million. We are also eligible to receive license payments totaling $21.0 million for the exercise of options with respect to the additional three product candidates that can be named under the Baxter Agreement, payments of $5.0 million each for extensions of the period during which such additional products may be selected, and a license payment of $7.0 million upon the achievement of pre-defined "minimum development" criteria, as defined in the agreement, for M834 (a selected biosimilar). In addition, we are eligible to receive an aggregate of approximately $316.0 million in potential milestone payments, comprised of (i) up to $66.0 million in substantive milestone payments upon achievement of specified technical and development milestone events across the five product candidates, and (ii) regulatory milestone payments totaling up to $250.0 million, on a sliding scale, across the five product candidates where, based on the products' regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval. Two of the technical and development milestones were time-based and the total eligible milestones have been adjusted to correspond to current development plans. There are no other time-based milestones included in the Baxter Agreement. The technical and development milestones include (i) achievement of certain criteria that will ultimately drive commercial feasibility for manufacturing the products and (ii) acceptance by the FDA of an IND or acceptance in the European Union of an equivalent application.

We continue to advance toward achievement of defined milestones in 2014 for the two biosimilar products under development with Baxter. For our lead biosimilar M923, the $12.0 million in milestones targeted for second half of 2014 are achievement of technical development criteria and the submission of a regulatory application in the European Union. The achievement of pre-defined "minimum development" criteria would generate a $7.0 million milestone payment for M834 in 2014.

In addition, if any of the five products are 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 each 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 the products, on a product-by-product and country-by-country basis, until there is no remaining payment obligation with respect to a 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;
- us in the event Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products within a certain time period;
- Baxter for its convenience; or
- us in the event Baxter does not exercise commercially reasonable efforts to commercialize a product in the United States or other specified countries, provided that we also have certain rights to directly commercialize such product, 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 have paid 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 following table summarizes the license maintenance fees and royalties paid to M.I.T. and recorded in the years ended December 31, 2013, 2012 and 2011 (in thousands):

| | 2013 | 2012 | 2011 |
|---|---|---|---|
| License maintenance fees | $ 82 | $ 183 | $ 158 |
| Royalties | 252 | 1,013 | 6,563 |
| Total | $334 | $1,196 | $6,721 |

Beginning in 2014, the annual license maintenance obligations, which extend through the life of the patents, are approximately $0.1 million per year.

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 if 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 and, if our agreement with M.I.T. is terminated, Sandoz agrees to assume our rights and obligations to M.I.T.

We previously had an exclusive patent license agreement dated October 31, 2002 with M.I.T granting us various licenses under certain patents solely related to the commercial sale or leasing of sequencing machines, including the performance of sequencing services. We terminated that agreement in January 2013. Nothing in the notice of termination impacts the agreement between us and M.I.T dated November 1, 2002.

**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 95 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 proteins 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 M402;
- methods to identify, analyze and characterize glycoproteins; and

- methods of manufacture of certain 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.

***Virdante***

In December 2011, we entered into an asset purchase agreement to acquire the sialylation technology assets of Virdante Pharmaceuticals, Inc., including intellectual property and cell lines, relating to the sialylation of IVIg and other proteins. We paid Virdante $4.5 million in cash at closing and have agreed to pay Virdante up to an aggregate of $51.5 million in additional contingent milestone payments upon achievement of particular development goals for up to three products in the manner and on the terms and conditions set forth in the purchase agreement. The contingent milestone payments are structured to include potential payments related to products based upon the acquired assets as follows: (i) no more than $30 million if certain development and regulatory milestones are achieved for an initial product; (ii) no more than $15 million if certain development and regulatory milestones are achieved for a second product; and (iii) no more than $6.5 million if certain development and regulatory milestones are achieved for a third product if the development milestones for such third product are met within fifteen (15) years of the date of the purchase agreement.

***Parivid***

In April 2007, we entered into an asset purchase agreement, or the 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 an 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, 2011 and 2012. The developed technology is being amortized over the estimated useful life of the Enoxaparin Sodium Injection developed technology of approximately 10 years.

## 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 the products covered by those agreements. Under the Baxter Agreement, Baxter is responsible for commercialization, including manufacturing, of the products covered by that agreement.

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 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 a 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.

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 new law 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, particularly the development and commercialization of complex generics and biosimilars due to existing brand competition at the time of product launch. 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.

Our Enoxaparin Sodium Injection product faces competition from Sanofi, the company currently marketing Lovenox, as well as from other companies with enoxaparin products. In October 2011, through its authorized third-party distributor, Sanofi-Aventis began marketing its generic version of Lovenox. In January 2012, Actavis and Amphastar launched an enoxaparin product. As a result of this competition, our Enoxaparin Sodium Injection product has lost market share and Sandoz has lowered its price. We may face more generic competition as ANDAs have been submitted to the FDA by Teva and Hospira, Inc., and other ANDAs or other regulatory applications may have been submitted or may be submitted in the future.

In addition to competition from Lovenox and other enoxaparin products, our Enoxaparin Sodium Injection product faces competition from other anticoagulants used to treat DVT and ACS. These competitive products include Factor Xa inhibitors, other LMWH products, and products in clinical development. The Factor Xa inhibitors include: GlaxoSmithKline plc's Arixtra®, which is approved in the prevention and treatment of several DVT indications, Bristol-Myers Squibb Company's apixaban (Eliquis®), which is approved in the United States for the reduction of risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation and rivaroxaban (Xarelto®), which is approved in the United States for DVT prophylaxis and the reduction of risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Xarelto® is marketed worldwide by Bayer AG and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. The Factor IIa inhibitors in development include Boehringer Ingelheim GmbH's dabigatran etexilate (Pradaxa®), which is currently approved to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation and is under review by FDA for DVT prophylaxis.

In the event that we receive approval to market M356, a generic version of Copaxone, we would face competition from a number of sources, including branded Copaxone, which is marketed worldwide by Teva Pharmaceutical Industries Ltd., or Teva. In addition, in January 2014, Teva's Supplemental NDA for a three-times-a-week formulation of Copaxone was approved by FDA. Teva's new formulation allows for a less frequent dosing regimen and will compete with our M356 product, if approved. We could also face competition from other companies if they receive marketing approval for generic versions of Copaxone. While there are no generic versions of Copaxone approved by the FDA to date, ANDAs 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. In addition, there are other products that currently compete with Copaxone in the United States. These include Rebif (interferon-beta-1a), which is co-promoted by EMD Serono Inc., a subsidiary of Merck Serono, a division of Merck KGaA, and Pfizer Inc. in the United States, and is marketed by Merck Serono in the European Union; Avonex (interferon beta-1a) and Tysabri (natalizumab), which are both marketed worldwide by Biogen Idec Inc.; Tecfidera, a novel oral compound, which is marketed by Biogen Idec Inc. in the United States, Canada and Australia and is approved but pending commercialization in the European Union; Betaseron (interferon-beta-1b), which is marketed by Bayer HealthCare Pharmaceuticals Inc., the pharmaceuticals affiliate of Bayer Schering Pharma AG, in the United States, and is marketed under the name Betaferon by Bayer Schering Pharma, a division of Bayer AG, in the European Union; Extavia (interferon-Beta-1b) and Gilenya™ (fingolimod), which are both marketed by Novartis Pharmaceuticals Corporation in the United States; Aubagio (teriflunomide), which is marketed by Sanofi in the United States and in the European Union; Novantrone (mitoxantrone for injection concentrate), which is marketed by EMD Serono, Inc.; and Lemtrada (alemtuzumab), a once annual infusion compound, which is marketed by Genzyme Corporation in the European Union but was declined approval by FDA in December 2013.

With the approval of the new biosimilar and interchangeable biologic pathway under Section 351(k) of the Public Health Service Act, many companies have announced their intention to develop and commercialize biosimilars. Amgen, Inc. has announced a collaboration with Actavis, Inc., Hospira has biosimilars agreements in place with Celltrion, Human Genome Sciences, NovaQuest Co-Investment Fund and Stada, Merck and Biogen Idec Inc. have announced collaborations with Samsung Bioepis, and Baxter has partnered with Coherus. Other companies expected to launch biosimilars in the United States include Sandoz, Biocon, Pfizer Inc., Roche, Boehringer Ingelheim and Teva. 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. There has been substantial growth in recent years in the number of generic and pharmaceutical companies looking to develop biosimilar (including potentially interchangeable) 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.

Similarly, our discovery work in oncology faces substantial competition from major pharmaceutical and other biotechnology companies that are actively working on improved and novel products.

The field of polysaccharides generally is a growing field with increased competition. However, the capabilities of the field can generally be segmented into those companies using polysaccharides as therapeutics, companies focused on engineering or modifying polysaccharides, including pegylation technologies, and companies focused on analytics. Among those in analytics, we are not aware of others that have similar capabilities for detailed chemical characterization of complex polysaccharides. We believe Procognia Limited's technology is largely focused on analyzing proteins and their glycosylation. In addition, many major pharmaceutical and biotechnology companies such as Amgen Inc. and Biogen Idec Inc. have successfully improved products through sugar modification. Potential competitors with broad glycobiology capabilities include Optimer Pharmaceuticals, Inc. (acquired by Cubist), Keryx Pharmaceuticals, Merck and Company, Inc. and Pro-Pharmaceuticals, Inc. as well as many private,

start-up pharmaceutical organizations. Many of these companies with polysaccharide capabilities are focused on providing services to pharmaceutical companies rather than focused on drug discovery and product development.

### Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2013, we had 269 employees, including 3 employees who hold M.D. degrees and 88 employees who hold Ph.D. degrees. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

### Financial Information about Segments and Geographic Areas

We have only one operating segment. See Part II, Item 6 for financial information about the segment. See also the section entitled "Segment Reporting" appearing in Note 2 to our consolidated financial statements for information about our segment and for financial information about geographic areas. 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 conditions 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, 2013, our accumulated deficit was $270.5 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 other 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.

***Our current product revenue is dependent on the continued successful manufacture and commercialization of Enoxaparin Sodium Injection.***

Our near-term ability to generate 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 or Teva related to Enoxaparin Sodium Injection is not successful, we may be liable for damages. In addition, third parties may be able to commercialize a generic Lovenox product 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 that we are entitled to damages for our lost profits due to infringing sales, and if Teva receives marketing approval, it will be able to commercialize a generic Lovenox. Under these circumstances, the resulting market price for our Enoxaparin Sodium Injection product may decline further and we may lose significant 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 patent extension amendments to unrelated federal legislation.

The FDA's practice is to rule within 180 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 180-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. Teva Neuroscience, Inc. has filed several Citizen Petitions regarding M356, of which the first four have been denied and dismissed. 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 other generic versions of our product candidates, including M356, 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 could decline.

***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's new formulation will compete with our M356 product. 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. 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 drug 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 they may claim that we are infringing those patents, including pursuit of Supreme Court review of the 2013 appellate ruling that patent claims previously asserted against us and Sandoz were invalid. If that occurs, we may incur significant expenses to respond to and litigate the 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 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.

***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, and 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.

***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 limit, scale back or cease our operations.***

As of December 31, 2013, we had cash, cash equivalents and marketable securities totaling $245.7 million. For the year ended December 31, 2013, we had a net loss of $108.4 million and cash used in operating activities of $86.8 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 may vary depending on the following:

- the level of sales of Enoxaparin Sodium Injection;
- a final decision, after appeal, is issued in favor of Teva in its 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 strategic collaborations;
- 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 our current programs and planned operating requirements principally through our current cash, cash equivalents and marketable securities. We believe that these funds will be sufficient to meet our operating requirements through at least 2015. We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and 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.

***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.

***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. While we currently maintain product liability insurance coverage that we believe is adequate for our current operations, we cannot be sure that such coverage 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.

***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 acquire or make investments in companies or technologies that could have an adverse effect on our business, results of operations and financial condition or cash flows.***

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.

**Risks Relating to Development and Regulatory Approval**

***If we are not able to obtain regulatory approval for commercial sale of our generic product candidate, M356, as a therapeutic equivalent to Copaxone, 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. 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. In addition, FDA is currently prohibited from granting final marketing approval until May 2014 as a result of ongoing patent litigation. 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. 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.

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. Depending on the timing and the extent of these funding, meeting and review disruptions, the Company's 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, and it is not determined to be unlawful or preempted by federal law, 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 M402, 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 M402 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 which 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 M402 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 was enacted in 2010 is being implemented that 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 new law 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. Assuming our products are approved for commercial sale, the new legislation could also have a positive impact on us by increasing the aggregate number of persons with health care coverage in the United States and expanding the market for our products, but such increases, if any, are unlikely to be realized until approximately 2014 at the earliest.

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 application 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. In addition, if a user fee statute is enacted, we may become liable for fees that could be material to our earnings.

**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.

Although we are aggressively pursuing patent applications on our innovative approaches to characterization and manufacture of complex generics, biosimilars and new drugs, there is presently uncertainty regarding the scope of the safe harbor from a patent infringement enforcement under federal patent law, 35 USC section 271(e)(1). This uncertainty 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, that give us rights to intellectual property that is 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 project, 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 could cause significant delays that could prevent us from completing the development and commercialization of such product. 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.

***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 all or a portion of the Agreement, the development and commercialization of some of our biosimilar candidates 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 us in the event Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products within a certain time period;
- by Baxter for its convenience (in whole or on a product by product basis);
- by us in the event Baxter does not exercise commercially reasonable efforts to commercialize a product in the United States or other specified countries, provided, that we also have certain rights to directly commercialize such product, 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 both of the initial two products 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 could cause significant delays that could prevent us from commercializing our biosimilar candidates. In addition, we may need to seek additional financing to support the research, development and commercialization of the terminated products or alternatively we may decide to discontinue the 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 the terminated products 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 the products in the territory.

***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 because 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.

## 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 ANDA or other announcements that indicated a material delay in the approval of the M356 ANDA;
- 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 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 our material 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 or 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

Not applicable.

## Item 2. PROPERTIES

As of February 5, 2014, 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<br>Cambridge, Massachusetts 02142 | 78,500 | Laboratory and Office | 04/30/2015 |
| 320 Bent Street<br>Cambridge, Massachusetts 02141 | 105,000 | Laboratory and Office | 08/31/2016 |
| | 183,500 | | |

**Item 3. LEGAL PROCEEDINGS**

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 M356. The suit alleged infringement related to four of the seven Orange Book patents listed for Copaxone and seeks declaratory and injunctive relief that would prohibit the launch of our product until the last to expire of these patents. 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 the present 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 patents listed 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. The Orange Book patents and one non-Orange book patent expire in May 2014 and one non-Orange Book patent expires in September 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35 U.S.C. section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz or Mylan ANDA prior to the expiration of the Orange Book patents. 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 the one patent set to expire in 2015. Several patents expiring in May 2014 remain in force. 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 in January 2014.

On December 10, 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and us for patent infringement related to certain other non-Orange Book patents seeking declaratory and injunctive relief that would prohibit the launch of our product until the last to expire of these patents as well as damages in the event that Sandoz has launched the product. In January 2010, we and Sandoz filed a motion to dismiss this second suit on several grounds and in July 2013, the motion to dismiss the suit was granted.

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 sodium 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 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, 2012 | $19.64 | $14.25 |
| June 30, 2012 | 17.09 | 13.00 |
| September 30, 2012 | 15.19 | 12.83 |
| December 31, 2012 | 14.85 | 10.05 |
| 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 |

***Holders***

On February 24, 2014, 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***

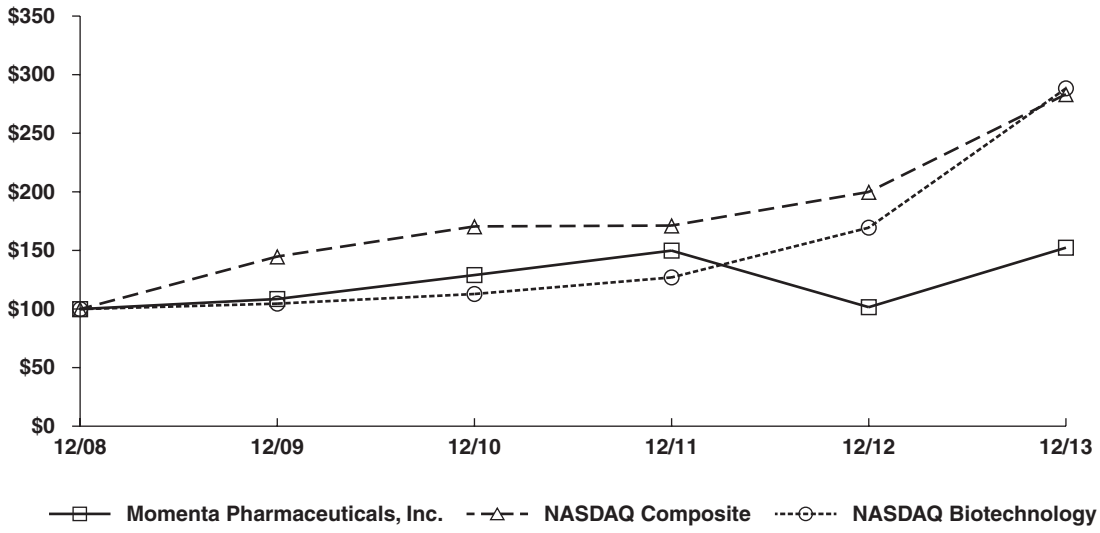
Information relating to compensation plans under which our equity securities are authorized for issuance is set forth in Item 12 below.

*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, 2008 through December 31, 2013, 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 12/31/08 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

| | 12/08 | 12/09 | 12/10 | 12/11 | 12/12 | 12/13 |
|---|---|---|---|---|---|---|
| **Momenta Pharmaceuticals, Inc.** | **100.00** | **108.62** | **129.05** | **149.91** | **101.64** | **152.41** |
| **NASDAQ Composite** | **100.00** | **144.88** | **170.58** | **171.30** | **199.99** | **283.39** |
| **NASDAQ Biotechnology** | **100.00** | **104.67** | **112.89** | **127.04** | **169.50** | **288.38** |

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 Securities Exchange Act of 1934, as amended, 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 Securities Exchange Act of 1934, as amended.

## Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data set forth below with respect to our statements of comprehensive (loss) income data for the years ended December 31, 2013, 2012 and 2011 and the balance sheet data as of December 31, 2013 and 2012 are derived from our audited financial statements included in this Annual Report on Form 10-K. The statements of comprehensive (loss) income data for the years ended December 31, 2010 and 2009 and the balance sheet data as of December 31, 2011, 2010 and 2009 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 at "Item 8. Financial Statements and Supplementary Data" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations," which are included elsewhere in this Annual Report on Form 10-K.

**Momenta Pharmaceuticals, Inc.**
**Selected Financial Data**

| | 2013 | 2012 | 2011 | 2010 | 2009 |
|---|---|---|---|---|---|
| | (in thousands, except per share information) | | | | |
| **Statements of Comprehensive (Loss) Income Data:** | | | | | |
| Collaboration revenues: | | | | | |
| Product revenue | $ 16,701 | $ 54,772 | $270,473 | $ 96,625 | $ — |
| Research and development revenue | 18,764 | 9,149 | 12,595 | 20,147 | 20,249 |
| Total collaboration revenue | 35,465 | 63,921 | 283,068 | 116,772 | 20,249 |
| Operating expenses: | | | | | |
| Research and development | 103,999 | 80,345 | 64,657 | 51,712 | 60,612 |
| General and administrative | 41,057 | 43,682 | 38,710 | 28,595 | 23,800 |
| Total operating expenses | 145,056 | 124,027 | 103,367 | 80,307 | 84,412 |
| Operating (loss) income | (109,591) | (60,106) | 179,701 | 36,465 | (64,163) |
| Interest income | 950 | 1,238 | 746 | 176 | 825 |
| Interest expense | — | — | (91) | (329) | (570) |
| Other income (expense) | 233 | 220 | — | 978 | (104) |
| Net (loss) income | $(108,408) | $(58,648) | $180,356 | $ 37,290 | $(64,012) |
| Net (loss) income per share: | | | | | |
| Basic | $ (2.13) | $ (1.16) | $ 3.62 | $ 0.84 | $ (1.60) |
| Diluted | $ (2.13) | $ (1.16) | $ 3.55 | $ 0.81 | $ (1.60) |
| Shares used in calculating net (loss) income per share: | | | | | |
| Basic | 50,907 | 50,411 | 49,852 | 44,626 | 40,056 |
| Diluted | 50,907 | 50,411 | 50,823 | 45,942 | 40,056 |
| Comprehensive (loss) income | $(108,494) | $(58,456) | $180,291 | $ 37,281 | $(64,433) |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2013 | 2012 | 2011 | 2010 | 2009 |
| **Balance Sheet Data:** | | | | | |
| Cash and cash equivalents | $ 29,766 | $ 52,990 | $ 49,245 | $ 100,681 | $ 21,934 |
| Marketable securities | 215,916 | 287,613 | 299,193 | 52,078 | 73,716 |
| Working capital | 243,649 | 339,006 | 383,393 | 196,650 | 85,753 |
| Total assets | 316,815 | 406,629 | 420,909 | 227,569 | 118,451 |
| Deferred revenue | 27,716 | 31,695 | 3,764 | 5,913 | 8,763 |
| Other liabilities | 19,262 | 14,447 | 14,067 | 15,553 | 15,526 |
| Total liabilities | 46,978 | 46,142 | 17,831 | 21,466 | 24,289 |
| Accumulated deficit | (270,459) | (162,051) | (103,403) | (283,759) | (321,049) |
| Total stockholders' equity | 269,837 | 360,487 | 403,078 | 206,103 | 94,162 |

## Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Our Management's Discussion and Analysis of Financial Condition and Results of Operations include the identification of certain trends and other statements that may predict or anticipate future business or financial results. There are important factors that could cause our actual results to differ materially from those indicated. See "Risk Factors" in Item 1A of this Annual Report on Form 10-K.

### Business Overview

***The Company***

We are a biotechnology company operating in three product areas: Complex Generics, Biosimilars and Novel Drugs. Our approach 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 based on this knowledge, analyze sets of biological data to evaluate the biological function of our products, and develop manufacturing processes that enable our products to be reliably produced. Our first product, developed in collaboration with Sandoz, Enoxaparin Sodium Injection, a generic version of Lovenox®, was approved in July 2010, validating the commercial value of our platform. In the period from commercial launch through September 2011, we capitalized on the advantage of having the only generic Lovenox in the marketplace and recognized over $340 million in revenue from this product.

***Our Programs***

The first product area we entered was complex generics. Our complex generics programs target marketed products that were originally approved by the United States Food and Drug Administration, or FDA, as New Drug Applications, or NDAs. Therefore, we have been able to access the existing 505(j) generic regulatory pathway and have submitted Abbreviated New Drug Applications, or ANDAs, for these products. Our first commercial product, Enoxaparin Sodium Injection, which has been developed and commercialized in collaboration with Sandoz Inc. and Sandoz AG, collectively Sandoz, affiliates of Novartis AG, received FDA marketing approval in July 2010 as a generic version of Lovenox® (enoxaparin sodium injection). Lovenox is a complex mixture of polysaccharide chains derived from naturally sourced heparin which is used to prevent and treat deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. The Enoxaparin Sodium Injection ANDA submitted by Sandoz was the first ANDA for a generic Lovenox to be approved by FDA, validating our novel approaches to the structural characterization, process engineering and biologic systems analysis of complex molecules. From July 2010 through early October 2011, the 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% profit share on Sandoz's sales of Enoxaparin Sodium Injection. The product now faces other generic competitors and we receive a royalty on net sales.

Our second complex generic product candidate, M356, is designed to be a generic version of Copaxone® (glatiramer acetate injection), a drug that is indicated for the reduction of the frequency of relapses in patients with relapsing-remitting multiple sclerosis, or RRMS. Copaxone consists of a synthetic mixture of polypeptide chains. With M356, we extended our core polysaccharide characterization and process engineering capabilities to develop capabilities for the structural characterization, process engineering and biologic systems analysis of this complex polypeptide mixture. We are also collaborating with Sandoz to develop and commercialize M356, and the Sandoz ANDA for M356 is currently under FDA review.

Our second product area is biosimilars, which is targeted toward developing biosimilar versions of marketed therapeutic proteins, with a goal of obtaining FDA designation as interchangeable. The subset of biosimilars receiving an interchangeability designation are known as interchangeable biologics.

In March 2010, an abbreviated regulatory process was codified in Section 351(k) of the Patient Protection and Affordable Care Act of 2010. This new pathway opened the market for biosimilar and interchangeable versions of a broad array of biologic therapeutics, including antibodies, cytokines, fusion proteins, hormones and other recombinant proteins. By 2015, sales of biosimilars are expected to reach between $1.9 billion to $2.6 billion. Most biologic therapies are complex mixtures, and for several years we have been investing in developing novel approaches to the structural characterization, process engineering and analysis of the biologic activities of these products. In February 2012, FDA released three documents containing their preliminary guidelines for applications under the Section 351(k) pathway. These guidelines state that FDA will use a step-wise review that considers the totality-of-the-evidence in determining extent of the clinical development program. This approach puts a substantial emphasis on structural and functional characterization data in evaluating biosimilar products for approval. We believe that our strategy for the development of biosimilars aligns well with the framework that the FDA has outlined in the draft guidance documents. Our goal is to engineer biologic products that will show minimal to no structural or functional differences from the reference brand product, thereby justifying a more selective and targeted approach to human clinical testing and to support demonstration of interchangeability. 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. Baxter is an established healthcare company with global product development, manufacturing and commercial capabilities.

Our third product area is novel drugs. M402, our novel drug in Phase 1 clinical development, is an oncology candidate derived from unfractionated heparin and engineered to have significantly reduced anticoagulant activity while preserving the anti-tumor properties of heparin. Nonclinical data showed potent binding of M402 to multiple growth factors, adhesion molecules, and chemokines to inhibit tumor progression, metastasis, and angiogenesis. In addition to this development candidate, we are also seeking to discover and develop additional novel drugs. We believe our core analytical tools and approach may enable new insights into the complex biology underlying many 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 drugs which may positively modulate multiple pathways in a disease.

***Our Collaborations***

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.

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 expanded the geographic markets for Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union. Further, under the Second Sandoz Collaboration Agreement, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356, among other products. In connection with the 2006 Sandoz Collaboration, 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, 2013, Novartis AG owned approximately 9% of our outstanding common stock.

Prior to the launch of Enoxaparin Sodium Injection in 2010, the collaboration revenues derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration primarily consisted of amounts earned by us for reimbursement by Sandoz of research and development services and development costs. In July 2010, Sandoz began the commercial sale of Enoxaparin Sodium Injection. The profit-share or royalties Sandoz is obligated to pay us under the 2003 Sandoz Collaboration differ depending 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 the 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 Court of Appeals for the Federal Circuit granting a stay of the preliminary injunction previously issued against them by the United States District Court, Watson Pharmaceuticals, Inc. (now Actavis, Inc., or Actavis) and Amphastar launched their third-party competitor enoxaparin product. Consequently, in each product year, for net sales of Enoxaparin Sodium Injection 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. Annual adjustments of $3.8 million, $3.9 million and $4.1 million, respectively, were recorded as a reduction in product revenue in the years ended December 31, 2013, 2012 and 2011, respectively.

In December 2011, we and Baxter entered into the Baxter Agreement under which we agreed to collaborate, on a world-wide basis, on the development and commercialization of biosimilars. The Baxter Agreement became effective in February 2012. Baxter is an established healthcare company with global product development, manufacturing and commercial capabilities. To accelerate efforts in the biosimilars space and address this growing global market, we significantly increased the headcount and related operating expenses dedicated to our biosimilars program in 2012 and 2013. We expect that the increase in operating expenses will be partially offset in future years by revenues from option fees and milestone payments under the Baxter Agreement, subject to achievement of technical and regulatory criteria.

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, which are:

- M923, a biosimilar for a branded biologic indicated for certain autoimmune and inflammatory diseases, is our most advanced biosimilar. We are working towards progressing this program to the clinic in Europe in the second half of 2014.
- M834, a biosimilar also indicated for certain autoimmune and inflammatory diseases. We are working toward achievement of a pre-defined "minimum development criteria" license payment in 2014.

In July 2012, Baxter selected a third product for inclusion in the collaboration, a monoclonal antibody for oncology which has been designated as M511. In December 2013, Baxter terminated its option to license M511 under the Baxter Agreement following an internal portfolio review. We continue to develop M511 as part of our biosimilars program. Baxter has the right, until February 2015, to select up to three additional biosimilars to be included in the collaboration. We may also consent, at our option, to allow Baxter to name a replacement product for M511, if Baxter requests such replacement.

As of December 31, 2013, we had an accumulated deficit of $270.5 million. To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates. In the second half of 2010, we began to derive revenue from our profit share on Sandoz's commercial sale of Enoxaparin Sodium Injection. Due to the launch by Actavis and Amphastar of their enoxaparin product in January 2012, our Enoxaparin Sodium Injection product revenue has significantly decreased and we have been incurring operating losses. We expect that our return to profitability, if at all, would most likely come from the commercialization of our generic Copaxone product, which is subject to FDA approval. Even if our generic Copaxone is approved, there can be no assurance that we will return to profitability. Unless and until generic Copaxone is approved, we expect to incur annual operating losses over the next several years as we expand our drug commercialization, development and discovery efforts. Even if our generic Copaxone is approved, there can be no assurance that we will return to profitability. Additionally, we plan to continue to evaluate possible acquisitions or licensing of rights to additional technologies, products or assets that fit within our growth strategy. Accordingly, we will need to generate significant revenue to return to profitability.

## Financial Operations Overview

***Years Ended December 31, 2013, 2012 and 2011***

***Collaboration Revenue***

Collaboration revenue includes product revenue and research and development revenue earned under our collaborative arrangements. Product revenue consists of profit share, royalties and commercial milestones earned from Sandoz on sales of Enoxaparin Sodium Injection following its commercial launch in July 2010. For the year ended December 31, 2013, we earned $16.7 million in royalties on Sandoz's reported net sales of Enoxaparin Sodium Injection of $213 million. For the years ended December 31, 2012 and 2011, we earned $54.8 million and $260.5 million, respectively, in part on a profit share and in part on a royalty on Sandoz's net sales of Enoxaparin Sodium Injection of $451 million and $1.0 billion, respectively. The decreases in our product revenue of $38.1 million, or 70%, and Sandoz's net sales of $238 million, or 53%, from the 2012 period to the 2013 period is due to decreased unit sales due to lower market share, and lower prices in response to competitor pricing reductions on enoxaparin. The decreases in our product revenue of $205.7 million, or 79%, and Sandoz's net sales of $549 million, or 55%, from the 2011 period to the 2012 period are due to a change in the contractual basis of our earned product revenues from profit share to royalty-based following the launch of an authorized generic in October 2011 and the January 2012 launch of a third-

party competitor's generic Lovenox®, as well as decreased unit sales due to lower market share and lower prices in response to competitor pricing reductions on enoxaparin. Additionally, in 2011 we earned a $10.0 million commercial milestone on the one-year anniversary of FDA approval of Enoxaparin Sodium Injection as sole generic.

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;
- under the 2006 Sandoz Collaboration for amortization of the equity premium;
- under the Baxter Agreement for reimbursement of research and development services and reimbursement of development costs; and
- under the Baxter Agreement for amortization of the $33 million upfront payment.

Research and development revenue for 2013 was $18.8 million, compared with $9.1 million for 2012 and $12.6 million for 2011. 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. The decrease in research and development revenue of $3.5 million, or 28%, from the 2011 period to the 2012 period is primarily due to a decrease in reimbursable manufacturing expenses associated with our M356 program offset by amortization of the upfront payment from Baxter.

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 2014 depending on our research and development activities. We expect to continue to amortize the $33.0 million upfront payment from Baxter as we deliver research and development services under the Baxter Agreement, with 2014 quarterly amortization of approximately $0.8 million related to the two licensed biosimilars.

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 the Sandoz 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. The change in Sandoz contractual payment terms, along with additional generic competition, has caused, and we expect will continue to cause, our future product revenue from Enoxaparin Sodium Injection to be significantly reduced compared to revenues earned during the product's exclusivity period.

***Research and Development Expense***

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. We expense research and development costs as incurred. 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 2013 was $104.0 million, compared with $80.3 million in 2012 and $64.7 million in 2011. 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 our M923 program; $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 increase of $15.6 million, or 24%, from the 2011 period to the 2012 period resulted from increases of: $5.7 million in personnel and related costs associated with our headcount growth to support our programs; $4.1 million in rent and facility-related expenses, principally due to the commencement in the first quarter of 2012 of a sublease for additional research and development space; $3.0 million in laboratory expenses in support of our programs; $2.5 million in clinical trial expenses associated with our M402 Phase 1/2 clinical study; $1.9 million in depreciation and amortization expense primarily due to increased capital expenditures to support our programs; $1.6 million in process development, manufacturing and third-party research costs related to our biosimilars and novel products programs; $0.9 million in share-based compensation expense associated with grants of stock awards to new hires; and $0.4 million in consulting fees in support of our programs. These increases were offset by a $4.5 million in-process research and development charge in 2011 related to the acquisition of sialylation technology assets. We expect future research and development expenses to increase in support of our product candidates.

The lengthy process of securing FDA approval for 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 amortization of our intangible assets, for each of our principal development programs for the years ended December 31, 2013, 2012 and 2011. 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.

| | Research and Development Expense (in thousands) | | | |
|---|---|---|---|---|
| | For the years ended December 31, | | | Project Inception to December 31, 2013 |
| Development Programs (Status) | 2013 | 2012 | 2011 | |
| M356 (ANDA Filed) | $ 2,525 | $ 3,880 | $ 6,618 | $47,087 |
| M402 (Phase 1/2) | 3,930 | 5,053 | 3,258 | 18,335 |
| Biosimilars (Development) | 24,501 | 7,440 | 875 | 35,939 |
| Discovery programs | 3,298 | 1,316 | 6,698 | |
| Research and development internal costs | 69,745 | 62,656 | 47,208 | |
| Total research and development expense | $103,999 | $80,345 | $64,657 | |

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 M402 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 proof-of-concept clinical study 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 discovery program external expenditures from the 2012 period to the 2013 period was primarily due to research collaborations we entered into to support our novel drug program.

The decrease of $2.7 million in M356 external expenditures from the 2011 period to the 2012 period was primarily due to timing of process development activities, manufacturing and third-party research costs. The increase of $1.8 million in M402 external expenditures from the 2011 period to the 2012 period was principally due to costs incurred in connection with the initiation of a Phase 1/2 proof-of-concept clinical study. The increase of $6.6 million in biosimilars external expenditures from the 2011 period to the 2012 period was due to the timing of process development and third-party research costs to fund the build-out of our biologics infrastructure to support product development under our Baxter collaboration. Discovery program external expenditures decreased by $5.4 million from the 2011 period to the 2012 period primarily due to a $4.5 million in-process research and development charge in 2011 related to the acquisition of sialylation technology assets.

Research and development internal costs consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation. The increases of $7.1 million from the 2012 period to the 2013 period and $15.4 million from the 2011 period to the 2012 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 executive, finance, legal, accounting, investor relations, information technology, business development and human resource functions. Other costs include royalty and license fees, facility and insurance costs not otherwise included in research and development expenses and professional fees for legal and accounting services and other general expenses.

General and administrative expense for the year ended December 31, 2013 was $41.1 million, compared to $43.7 million in 2012 and $38.7 million in 2011. 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 Enoxaparin Sodium Injection patent litigation. General and administrative expense increased by $5.0 million, or 13%, from the 2011 period to the 2012 period due to increases of: $6.4 million in professional fees principally due to increased legal fees relating to Enoxaparin Sodium Injection patent litigation and increase in consultant fees; $1.7 million in personnel and related costs associated with our headcount growth; $1.7 million in share-based compensation expense principally associated with increased headcount; and $0.7 million in other general and administrative expense for an insurance bond premium paid related to Enoxaparin Sodium Injection patent litigation and renewals of vendor maintenance agreements. These increases were offset by a decrease of $5.5 million in royalty fees payable primarily to Massachusetts Institute of Technology, or M.I.T., due to reduced Enoxaparin Sodium Injection product revenue.

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 $1.0 million, $1.2 million and $0.7 million for the years ended December 31, 2013, 2012 and 2011, respectively. The decrease of $0.2 million from the 2012 period to the 2013 period was primarily due to lower average investment balances. The increase of $0.5 million from the 2011 period to the 2012 period was primarily due to higher average investment balances due to the upfront payment made by Baxter in the first quarter of 2012 and cash received from Sandoz for Enoxaparin Sodium Injection product revenues.

*Interest Expense*

Interest expense was zero, zero and $0.1 million for the years ended December 31, 2013, 2012 and 2011, respectively. The decrease of $0.1 million from the 2011 period to the 2012 period was due to the completion of repayment schedules on our equipment line of credit during 2011.

*Other Income*

Other income was $0.2 million, $0.2 million and zero for the years ended December 31, 2013, 2012 and 2011, respectively. 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, 2013 and 2012.

**Liquidity and Capital Resources**

We have financed our operations since inception primarily through the sale of equity securities, payments from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, including profit share/royalty payments related to sales of Enoxaparin Sodium Injection, and borrowings from our lines of credit and capital lease obligations. Since our inception, we have received $406 million through private and public issuance of equity securities. As of December 31, 2013, we had received a cumulative total of $576 million from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, a $33.0 million upfront payment under the Baxter Agreement, $4.0 million from debt financing, $9.2 million from capital lease obligations and $3.9 million from our landlord for leasehold improvements related to our corporate facility and additional funds from interest income. The January 2012 launch of a third-party competitor's enoxaparin product triggered a change under the terms of our agreement with Sandoz in the basis of our product revenue from profit share to a royalty that is based on Sandoz's net sales of Enoxaparin Sodium Injection. This competition and the resulting contractual change significantly reduced our revenues and resulted in us incurring operating losses. We expect that our return to profitability, if at all, will most likely come from the commercialization of our generic Copaxone product, which is subject to FDA approval. However, Teva's three-times a week formulation of Copaxone, which received FDA marketing approval in January 2014, could reduce our potential sales of our generic Copaxone product, and cause our return to profitability to be more uncertain. We expect to finance our current programs and planned operating requirements principally through our current cash, cash equivalents and marketable securities. We believe that these funds will be sufficient to meet our operating requirements through at least 2015. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and other important factors, and actual results could vary materially. We may, from time to time, seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources.

At December 31, 2013, we had $245.7 million in cash, cash equivalents and marketable securities and $13.1 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, 2013 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, 2013.

During the year ended December 31, 2013, our operating activities used cash of $86.8 million. During the years ended December 31, 2012 and 2011, our operating activities provided cash of $9.0 million and $213.7 million, respectively. The cash provided by or used for operating activities generally approximates our net (loss) income adjusted for non-cash items and changes in operating assets and liabilities.

For the year ended December 31, 2013, our net loss adjusted for non-cash items was $83.6 million. For the year ended December 31, 2013, non-cash items include share-based compensation of $12.8 million, depreciation and amortization of our property, equipment and intangible assets of $8.2 million and amortization of purchased premiums on our marketable securities of $3.6 million. 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 related to the $33.0 million upfront payment made to us by Baxter in 2012 under our collaboration; 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.

For the year ended December 31, 2012, our net loss adjusted for non-cash items was $34.1 million. For the year ended December 31, 2012, non-cash items include share-based compensation of $13.7 million, depreciation and amortization of our property, equipment and intangible assets of $7.5 million and amortization of purchased premiums on our marketable securities of $3.3 million. 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 M402 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.

For the year ended December 31, 2011, our net income adjusted for cash and non-cash items was $203.4 million. For the year ended December 31, 2011, cash and non-cash items include share-based compensation of $11.1 million, the acquisition of sialylation technology assets of $4.5 million, depreciation and amortization of our property, equipment and intangible assets of $5.5 million, amortization of purchased premiums on our marketable securities of $1.7 million, and losses on disposals of fixed assets of $0.2 million. In addition, the net change in our operating assets and liabilities provided cash of $10.3 million and resulted from: a decrease in accounts receivable of $26.3 million, due to a decrease in Sandoz's net sales of Enoxaparin Sodium Injection, due primarily to lower unit pricing, and by a contractual change in the basis of calculating our Enoxaparin Sodium Injection product revenue, both related to the launch of an authorized generic Lovenox in October 2011; a decrease in unbilled revenue of $2.5 million, resulting from lower fourth-quarter reimbursable manufacturing activities for our M356 program; an increase in prepaid expenses and other current assets of $0.7 million, primarily due to advance payments made for renewals of vendor maintenance agreements; an increase in restricted cash of $15.7 million principally due to the $17.5 million of cash collateral for a security bond posted in the Enoxaparin Sodium Injection patent litigation; and a decrease in deferred revenue of $2.1 million, due to the amortization of the $13.6 million equity premium paid by Novartis Pharma AG in connection with the 2006 Sandoz Collaboration.

During the year ended December 31, 2013, our investing activities provided cash of $58.6 million. In the year ended December 31, 2013, we received $294.2 million from maturities of marketable securities and $3.8 million from sales of marketable securities. Additionally, during the year ended December 31, 2013, we used $230 million of cash to purchase marketable securities and $9.5 million for the purchase of laboratory equipment and leasehold improvements.

Net cash used in investing activities was $7.4 million for the year ended December 31, 2012. During the year ended December 31, 2012, we received $523.6 million from maturities of marketable securities and we used $515.1 million of cash to purchase marketable securities. During 2012, we used $9.6 million for the purchase of laboratory equipment for our biosimilar and novel products programs, $3.6 million for leasehold improvements related to our subleased space at 675 West Kendall Street and software for our business operations, and $2.3 million for leasehold improvements, furniture and computer equipment related to additional subleased laboratory and office space.

Net cash used in investing activities was $268.7 million for the year ended December 31, 2011. During the year ended December 31, 2011, we used $551.2 million of cash to purchase marketable securities and we received $302.4 million from maturities of marketable securities. During 2011, we paid $6.7 million as consideration for Parivid's completion and satisfaction of a milestone related to our Enoxaparin Sodium Injection developed technology, and we used $4.5 million to acquire sialylation technology assets and $8.7 million to purchase laboratory equipment and leasehold improvements.

Net cash provided by financing activities was $5.0 million, $2.2 million and $3.6 million for the years ended December 31, 2013, 2012 and 2011, respectively. During 2013, 2012 and 2011, we received net proceeds of $5.0 million, $2.2 million and $5.5 million, respectively, from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan. During 2011,

these proceeds were offset by principal payments of $1.7 million on our capital lease agreement obligations and $0.2 million on financed leasehold improvements related to our subleased space at 675 West Kendall Street.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2013 (in thousands):

| Contractual Obligations | Total | 2014 | 2015 through 2016 | 2017 through 2018 | After 2018 |
|---|---|---|---|---|---|
| License maintenance obligations | $ 413 | $ 83 | $ 165 | $165 | * |
| License royalty obligations | 300 | 60 | 120 | 120 | * |
| Operating lease obligations | 23,268 | 10,986 | 12,199 | 83 | $— |
| Total contractual obligations | $23,981 | $11,129 | $12,484 | $368 | $— |

* After 2018, the annual obligations, which extend through the life of the patents are approximately $0.1 million per year.

**Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of revenues and expenses during the reporting periods. Additionally, we are required to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the balance sheet dates. On an on-going basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses and share-based payments. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values 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 the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

***Revenue Recognition***

We recognize revenue in accordance with Financial Accounting Standard, or FASB, Accounting Standards Codification, or ASC, 605, Revenue Recognition, which requires that certain criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

*Collaborative Agreements*

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.

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 expanded the geographic markets for Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union. Further, under the Second Sandoz Collaboration Agreement, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356, among other products.

In December 2011, we and Baxter entered into the Baxter Agreement under which we agreed to collaborate, on a world-wide basis, on the development and commercialization of 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 biosimilar products, M923 and M834, indicated in the inflammatory and autoimmune therapeutic areas. In July 2012, Baxter selected a third product for inclusion in the collaboration, a monoclonal antibody for oncology which has been designated as M511. In December 2013, Baxter terminated its option to license M511 under the Baxter Agreement following an internal portfolio review. We and Baxter are continuing to collaborate on M923 and M834 and evaluate additional products for development. We continue to develop M511 as part of our biosimilars program.

Under the terms of collaboration agreements entered into by us, we have received and may continue to receive non-refundable, up-front license fees, funding or reimbursement of research and development efforts, license and milestone payments if specified objectives are achieved and/or profit-sharing or royalties on product sales.

*Product Revenue*

Profit share and/or royalty revenue is reported as product revenue and is recognized based upon net sales or profit share 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.

*Research and Development Revenue*

We apply the guidance pursuant to FASB's Accounting Standards Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements (Topic 615), for all multiple-element arrangements entered into on or after January 1, 2011 and for any multiple-element arrangements that were entered into prior to January 1, 2011 but materially modified on or after January 1, 2011. ASU No. 2009-13 amends the guidance on the accounting for arrangements involving the delivery of more than one element and addresses the determination of the unit(s) of accounting for multiple-element arrangements and how the arrangement's consideration should be allocated to each unit of accounting. Pursuant to ASU No. 2009-13, we evaluate each deliverable to determine if it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price, and (iii) best estimate of the selling price, or BESP. The BESP reflects our best estimate of what the selling price would be if the deliverable was regularly sold on a stand-alone basis. We expect, in general, to use BESP for allocating consideration to each deliverable. In general, the consideration allocated to each unit of accounting is then recognized as the related goods or services are delivered and limited to the consideration not contingent upon future deliverables. We applied ASU No. 2009-13 to the Baxter Agreement.

In accordance with ASU No. 2009-13, we 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 and the four additional biosimilars, (ii) the research and development services related to the two initial biosimilars and the four additional biosimilars and (iii) our participation in the joint steering committee. We 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 our performance of research and development services. As such, we 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 first initial 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 has been allocated to the second initial 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. In December 2013, Baxter terminated its option to license M511, a named product under the Baxter Agreement. Accordingly, the expected consideration to be received under the arrangement has been reduced by $7.0 million (M511 option payment) and there is now one less deliverable. We determined that the change in expected consideration to be received under the arrangement represents a change in estimate and, as a result, we reallocated the revised expected consideration of $54.0 million to the remaining deliverables under the agreement using the original BESP. We will recognize the resulting change in revenue on a prospective basis. Of the $54.0 million, $11.0 million was allocated to the first initial 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 million has been allocated to the second initial 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.

We will commence revenue recognition for each of the five units of accounting related to the products upon delivery of the related development and product license and will record this revenue on a straight-line basis over the applicable performance period during which the research and development services will be delivered. We will recognize the revenue related to the joint steering committee deliverable over the applicable performance period during which the research and development services will be delivered. We determined that the performance period for each of the combined five units of accounting consisting of the products and related research and development services begins upon delivery of the related development and product license and ends upon FDA approval of the related product. We determined that the applicable performance period for the joint steering committee deliverable begins upon delivery of the first development and product license and ends upon the latest date of FDA approval. We currently estimate that the performance period for the two initial products, considering their respective stage of development, is approximately five and eight years, respectively, and the period of performance for the joint steering committee is approximately eleven years.

Under the 2003 Sandoz Collaboration and the Second Sandoz Collaboration Agreement, we have received and may continue to receive consideration in the form of non-refundable, upfront fees related to intellectual property rights and licenses, funding or reimbursement of research and development

efforts, milestone payments if specified objectives are achieved and profit-sharing or royalties on product sales. We are 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. These multiple-element arrangements were entered into prior to January 1, 2011 and have not been materially modified thereafter; therefore we continue to apply our prior accounting policy with respect to the non-refundable, upfront license fees and research and development services for these arrangements. Under this prior accounting policy, in general, revenue from non-refundable, upfront fees related to intellectual property rights and licenses where we have continuing involvement is recognized ratably over the estimated period of ongoing involvement, which is typically the development term, because there was no objective and reliable evidence of fair value for any undelivered item to allow the delivered item to be considered a separate unit of accounting. Research and development funding is recognized as earned over the period of effort.

Under the Baxter Agreement, we have received consideration in the form of a non-refundable, upfront fee related to intellectual property rights and licenses and we have received and may continue to receive funding or reimbursement of research and development efforts. Additionally, we may receive consideration in the form of profit-sharing or royalties on product sales.

Under the 2003 Sandoz Collaboration, we have received consideration in the form of milestone payments and under the Second Sandoz Collaboration Agreement and the Baxter Agreement we may receive consideration in the form of milestone payments in future periods if specified objectives are achieved. We apply the guidance pursuant to ASU No. 2010-17, Revenue Recognition—Milestone Method, for all sales-based, commercial and research and development milestones achieved. In accordance with ASU No. 2010-17, at the inception of each arrangement that includes milestone payments, we evaluate each milestone to determine whether (a) the milestone can only be achieved based in whole or in part on either (i) our performance or (ii) on the occurrence of a specific outcome resulting from our performance, (b) there is considerable uncertainty at the date the arrangement is entered into that the event will be achieved and (c) the achievement of the event would result in additional payments being due to us.

Additionally, we evaluate whether each milestone is considered "substantive." We designate a milestone as "substantive" only if it meets all of the following three criteria (i) the consideration is commensurate with either (a) our performance to achieve the milestone or (b) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

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 and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. We have concluded that all of the development and regulatory milestones pursuant to the 2003 Sandoz Collaboration and the Second Sandoz Collaboration Agreement are substantive. We determined certain of the development milestones and all of the regulatory milestones under the Baxter Agreement are substantive. Revenues from development and regulatory milestones, if they are non-refundable and deemed substantive, are recognized upon successful accomplishment of the milestones as research and development revenue. Milestones that are not considered substantive are accounted for as license payments and are evaluated as such in accordance with ASU No. 2009-13. 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.

***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, 2013 and December 31, 2012.

During the years ended December 31, 2013 and 2012, 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, 2013 and December 31, 2012. 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 Expenses***

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and then estimating the level of service performed and the associated cost incurred for such service as of each balance sheet date in our financial statements. Examples of estimated expenses for which we accrue include contract service fees paid to contract research organizations for process development and manufacturing. In connection with such service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual levels of services incurred by such service providers. The majority of our service providers invoice us monthly in arrears for services performed. In the event that we do not identify certain costs, which have begun to be incurred, or we under- or over-estimate the level of services performed or the costs of such services, our reported expenses for such period would be too low or too high. The date on which certain services commence, the level of services performed on or before a given date and the cost of such services are often determined based on subjective judgments. We make these judgments based upon the facts and circumstances known to us in accordance with generally accepted accounting principles.

***Share-Based Compensation***

We recognize the fair value of share-based compensation in our consolidated statements of comprehensive (loss) income. 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, 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-Merton option-pricing model requires us to develop certain subjective assumptions including the expected volatility of our stock, the expected term of the award and the expected forfeiture rate associated with our stock option plan. 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.

The expected term of awards represents the period of time that the awards are expected to be outstanding. We use a blend of our 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, 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. The risk-free interest rate for periods within the contractual life of the option is based on the United States Treasury yield curve in effect at the time of grant.

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 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 2010, except to the extent that in the future we utilize net operating losses or tax credit carryforwards that originated before 2010. As of December 31, 2013, we were not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

**Recently Issued 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, 2013, 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, 2013 and 2012, and the related consolidated statements of comprehensive (loss) income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013. 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, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, 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, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated February 28, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 28, 2014

**MOMENTA PHARMACEUTICALS, INC.**

**CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share amounts)

| | December 31, | |
|---|---|---|
| | 2013 | 2012 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 29,766 | $ 52,990 |
| Marketable securities | 215,916 | 287,613 |
| Accounts receivable | 13,095 | 10,811 |
| Unbilled revenue | 3,413 | 800 |
| Prepaid expenses and other current assets | 3,401 | 4,953 |
| Total current assets | 265,591 | 357,167 |
| Property and equipment, net | 24,699 | 22,380 |
| Restricted cash | 20,719 | 19,971 |
| Intangible assets, net | 5,650 | 6,711 |
| Other long-term assets | 156 | 400 |
| Total assets | $ 316,815 | $ 406,629 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 6,307 | $ 3,580 |
| Accrued expenses | 11,447 | 9,641 |
| Deferred revenue | 3,692 | 4,426 |
| Other current liabilities | 496 | 514 |
| Total current liabilities | 21,942 | 18,161 |
| Deferred revenue, net of current portion | 24,024 | 27,269 |
| Other long-term liabilities | 1,012 | 712 |
| Total liabilities | 46,978 | 46,142 |
| Commitments and contingencies (Note 14) | | |
| **Stockholders' Equity:** | | |
| Preferred stock, $0.01 par value per share; 5,000 shares authorized at December 31, 2013 and 2012, 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, 2013 and 2012, 52,357 and 51,709 shares issued and outstanding at December 31, 2013 and 2012, respectively | 5 | 5 |
| Additional paid-in capital | 540,266 | 522,422 |
| Accumulated other comprehensive income | 25 | 111 |
| Accumulated deficit | (270,459) | (162,051) |
| Total stockholders' equity | 269,837 | 360,487 |
| Total liabilities and stockholders' equity | $ 316,815 | $ 406,629 |

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

**MOMENTA PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME**

(in thousands, except per share amounts)

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2013** | **2012** | **2011** |
| Collaboration revenues: | | | |
| Product revenue | $ 16,701 | $ 54,772 | $270,473 |
| Research and development revenue | 18,764 | 9,149 | 12,595 |
| Total collaboration revenue | 35,465 | 63,921 | 283,068 |
| Operating expenses: | | | |
| Research and development* | 103,999 | 80,345 | 64,657 |
| General and administrative* | 41,057 | 43,682 | 38,710 |
| Total operating expenses | 145,056 | 124,027 | 103,367 |
| Operating (loss) income | (109,591) | (60,106) | 179,701 |
| Other income (expense): | | | |
| Interest income | 950 | 1,238 | 746 |
| Interest expense | — | — | (91) |
| Other income | 233 | 220 | — |
| Total other income | 1,183 | 1,458 | 655 |
| Net (loss) income | $(108,408) | $(58,648) | $180,356 |
| Net (loss) income per share: | | | |
| Basic | $ (2.13) | $ (1.16) | $ 3.62 |
| Diluted | $ (2.13) | $ (1.16) | $ 3.55 |
| Weighted average shares outstanding: | | | |
| Basic | 50,907 | 50,411 | 49,852 |
| Diluted | 50,907 | 50,411 | 50,823 |
| Comprehensive (loss) income: | | | |
| Net (loss) income | $(108,408) | $(58,648) | $180,356 |
| Net unrealized holding (losses) gains on available-for-sale marketable securities | (86) | 192 | (65) |
| Comprehensive (loss) income | $(108,494) | $(58,456) | $180,291 |
| * Non-cash share-based compensation expense included in operating expenses is as follows: | | | |
| Research and development | $ 5,520 | $ 5,832 | $ 4,919 |
| General and administrative | $ 7,302 | $ 7,880 | $ 6,219 |

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, 2010 | 49,747 | $ 5 | $489,873 | $(16) | $(283,759) | $ 206,103 |
| Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan | 568 | — | 5,546 | — | — | 5,546 |
| Issuance of restricted stock | 1,021 | — | — | — | — | — |
| Cancellation of restricted stock | (51) | — | — | — | — | — |
| Share-based compensation expense for employees | — | — | 10,945 | — | — | 10,945 |
| Share-based compensation expense for non-employees | — | — | 193 | — | — | 193 |
| Unrealized loss on marketable securities | — | — | — | (65) | — | (65) |
| Net income | — | — | — | — | 180,356 | 180,356 |
| 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 |

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, | | |
|---|---|---|---|
| | 2013 | 2012 | 2011 |
| **Cash Flows from Operating Activities:** | | | |
| Net (loss) income | $(108,408) | $ (58,648) | $ 180,356 |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: | | | |
| In-process research and development expense related to acquisition of sialylation technology assets | — | — | 4,500 |
| Depreciation and amortization | 7,108 | 6,419 | 4,137 |
| Share-based compensation expense | 12,822 | 13,712 | 11,138 |
| Amortization of premium on investments | 3,575 | 3,288 | 1,677 |
| Amortization of intangibles | 1,061 | 1,061 | 1,378 |
| Impairment of equity investment | 244 | — | — |
| Loss on disposal of assets | 23 | 19 | 238 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (2,284) | 17,360 | 26,314 |
| Unbilled revenue | (2,613) | 1,965 | 2,500 |
| Prepaid expenses and other current assets | 1,552 | (2,406) | (754) |
| Restricted cash | (748) | (2,471) | (15,722) |
| Other assets | — | 389 | (389) |
| Accounts payable | 2,727 | (1,129) | 315 |
| Accrued expenses | 1,806 | 510 | 33 |
| Deferred revenue | (3,979) | 27,931 | (2,149) |
| Deferred lease incentives | 747 | — | — |
| Other current liabilities | (267) | 482 | 9 |
| Other long-term liabilities | (198) | 517 | 144 |
| Net cash (used in) provided by operating activities | (86,832) | 8,999 | 213,725 |
| **Cash Flows from Investing Activities:** | | | |
| Purchase of equity investment | — | (400) | — |
| Acquisition of sialylation technology assets | — | — | (4,500) |
| Milestone payment related to Parivid for developed technology | — | — | (6,664) |
| Purchases of property and equipment | (9,450) | (15,491) | (8,699) |
| Purchases of marketable securities | (229,969) | (515,088) | (551,272) |
| Proceeds from maturities of marketable securities | 294,183 | 523,572 | 302,415 |
| Proceeds from sales of marketable securities | 3,822 | | |
| Net cash provided by (used in) investing activities | 58,586 | (7,407) | (268,720) |
| **Cash Flows from Financing activities:** | | | |
| Proceeds from issuance of common stock under stock plans | 5,022 | 2,153 | 5,546 |
| Payments on financed leasehold improvements | — | — | (258) |
| Principal payments on capital lease obligations | — | — | (1,729) |
| Net cash provided by financing activities | 5,022 | 2,153 | 3,559 |
| (Decrease) increase in cash and cash equivalents | (23,224) | 3,745 | (51,436) |
| Cash and cash equivalents, beginning of period | 52,990 | 49,245 | 100,681 |
| Cash and cash equivalents, end of period | $ 29,766 | $ 52,990 | $ 49,245 |
| **Supplemental Cash Flow Information:** | | | |
| Cash paid for interest | $ — | $ — | $ 91 |

The accompanying notes are an integral part of these 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 specializing in the structural characterization, process engineering and biologic systems analysis of complex molecules in three product areas—complex generics, biosimilars and novel drugs. 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 in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 605, Revenue Recognition, which requires that certain criteria must be met before revenue can be recognized: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

*Collaborative Agreements*

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 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.

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 expanded the geographic markets for Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union. Further, 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.

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, related to the development and commercialization of biosimilars. The Company refers to this agreement as the Baxter Agreement.

Under the terms of collaboration agreements entered into by the Company, the Company has received and may continue to receive non-refundable, up-front license fees, funding or reimbursement of research and development efforts, license and milestone payments if specified objectives are achieved and/or profit-sharing or royalties on product sales.

*Product Revenue*

Profit share and/or royalty revenue is reported as product revenue and is recognized based upon net sales or profit share 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.

*Research and Development Revenue*

The Company applies the guidance pursuant to FASB Accounting Standards Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements (Topic 615), for all multiple-element arrangements entered into on or after January 1, 2011 and for any multiple-element arrangements that were entered into prior to January 1, 2011 but materially modified on or after January 1, 2011. ASU No. 2009-13 amends the guidance on the accounting for arrangements involving the delivery of more than one element and addresses the determination of the unit(s) of accounting for multiple-element arrangements and how the arrangement's consideration should be allocated to each unit of accounting. Pursuant to ASU No. 2009-13, the Company evaluates each deliverable to determine if it qualifies as a separate unit of accounting. This determination is generally based on whether the deliverable has "stand-alone value" to the customer. The arrangement's consideration is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The estimated selling price of each deliverable is determined using the following hierarchy of values: (i) vendor-specific objective evidence of fair value, (ii) third-party evidence of selling price, and (iii) best estimate of the selling price, or BESP. The BESP reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold on a stand-alone basis. The Company expects, in general, to use BESP for allocating consideration to each deliverable. In general, the consideration allocated to each unit of accounting is then recognized as the related goods or services are delivered and limited to the consideration not contingent upon future deliverables. The Company applied ASU No. 2009-13 to the Baxter Agreement.

Under the 2003 Sandoz Collaboration and the Second Sandoz Collaboration Agreement, the Company has received and may continue to receive consideration in the form of non-refundable, upfront fees related to intellectual property rights and licenses, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved and profit-sharing or royalties on product sales. These multiple-element arrangements were entered into prior to January 1,

2011 and have not been materially modified thereafter; therefore the Company continues to apply its prior accounting policy with respect to the non-refundable, upfront license fees and research and development services for these arrangements. Under this prior accounting policy, in general, revenue from non-refundable, upfront fees related to intellectual property rights and licenses where the Company has continuing involvement is recognized ratably over the estimated period of ongoing involvement, which is typically the development term, because there was no objective and reliable evidence of fair value for any undelivered item to allow the delivered item to be considered a separate unit of accounting. Research and development funding is recognized as earned over the period of effort.

Under the 2003 Sandoz Collaboration, the Company has received consideration in the form of milestone payments. 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. Under the Second Sandoz Collaboration Agreement and the Baxter Agreement the Company may receive consideration in the form of milestone payments in future periods. Under the Second Sandoz Collaboration Agreement, 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 the products under the collaboration, which include: a $10.0 million regulatory milestone payment related to the approval by the FDA of M356, and $153.0 million in sales-based and commercial milestone payments, of which up to $140.0 million (including the M356 regulatory milestone) are U.S.-based milestones. Under the Baxter Agreement, the Company is eligible to receive an aggregate of approximately $316.0 million in potential milestone payments, comprised of (i) up to $66.0 million in milestone payments upon achievement of specified technical and development milestone events across the five product candidates, and (ii) regulatory milestone payments totaling up to $250.0 million, on a sliding scale, across the five product candidates where, based on the products' regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval. The Company applies the guidance pursuant to ASU No. 2010-17, Revenue Recognition—Milestone Method, for all sales-based, commercial and research and development milestones achieved. In accordance with ASU No. 2010-17, at the inception of each arrangement that includes milestone payments, the Company evaluates each milestone to determine whether (a) the milestone can only be achieved based in whole or in part on either (i) the Company's performance or (ii) on the occurrence of a specific outcome resulting from its performance, (b) there is considerable uncertainty at the date the arrangement is entered into that the event will be achieved and (c) the achievement of the event would result in additional payments being due to the Company.

Additionally, the Company evaluates whether each milestone is considered "substantive." The Company designates a milestone as "substantive" only if it meets all of the following three criteria (i) the consideration is commensurate with either (a) the Company's performance to achieve the milestone or (b) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from its performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) 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 and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. The Company has concluded that the regulatory milestone pursuant to its 2006 Sandoz Collaboration is substantive. The Company has concluded that certain of the technical and development milestones and all of the regulatory milestones pursuant to the Baxter Agreement are substantive. Revenues from non-refundable technical, development and regulatory milestones will be recognized upon successful accomplishment of the milestones as research and

development revenue. Milestones that are not considered substantive are accounted for as license payments and are evaluated as such in accordance with ASU No. 2009-13. 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.

***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 invests its excess cash balance 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 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, 2013 as it has the ability and intent to hold these investments to maturity and it is unlikely 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, 2013, 2012 and 2011. 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, 2012 or 2011.

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 composed of money market funds carried at fair value, which approximates cost at December 31, 2013 and 2012.

***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, 2013 and December 31, 2012.

The carrying amounts reflected in the Company's 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.

***Concentration of Credit Risks***

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

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.

***Accounts Receivable and Unbilled Revenue***

Accounts receivable represents amounts due to the Company at December 31, 2013 and December 31, 2012 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, 2013 and December 31, 2012 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.

***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, 2013.

***Research and Development***

Research and development costs are expensed as incurred. 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.

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) income. Share-based compensation expense primarily relates to stock options, restricted stock and stock issued under its stock option plans and employee stock purchase plan. The Company recognizes share-based compensation expense equal to the fair value of stock options on a straight-line basis over the requisite service period. Restricted stock awards are recorded as compensation cost, based on the market value on the date of the grant, on a straight-line basis over each award's explicit or implicit service periods. 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 employee stock purchase plan.

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 contractual life 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 using the Company's estimate of fair value at each balance sheet date.

***Net (Loss) Income Per Share***

The Company computes basic net (loss) income per common share by dividing net (loss) income by the weighted average number of common shares outstanding, which includes common stock issued as a result of public offerings, stock option exercises, stock purchased under the Company's employee stock purchase plan and vesting of shares of restricted common stock. The Company computes diluted net (loss) income per common share by dividing net (loss) income 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 determines its 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.

The Company applies 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. The Company recognizes any material interest and penalties related to unrecognized tax benefits in income tax expense.

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 2010, except to the extent that in the future it utilizes net operating losses or tax credit carry forwards that originated before 2010. As of December 31, 2013, the Company was not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

***Comprehensive (Loss) Income***

In February 2013, the FASB issued ASU No. 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified out of Accumulated Other Comprehensive Income. ASU No. 2013-02 sets requirements for presentation for significant items reclassified to net income in their entirety during the period and for items not reclassified to net income in their entirety during the period. Further, ASU No. 2013-02 requires companies to present information about reclassifications out of accumulated other comprehensive income in one place. Also, companies are required to present reclassifications by component when reporting changes in accumulated other comprehensive income balances. The Company adopted ASU No. 2013-02 in 2013. ASU No. 2013-02 did not have a material impact on its results of operations or financial position.

Comprehensive (loss) income 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 (loss) income 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) income for relevant disclosures.

The following tables summarize the changes in accumulated other comprehensive income (loss) during the years ended December 31, 2013 and December 31, 2012 (in thousands):

| | Unrealized Gains (Losses) on Securities Available for Sale |
|---|---|
| Balance as of January 1, 2012 | $(81) |
| Other comprehensive income before reclassifications | 192 |
| Amounts reclassified from accumulated other comprehensive income | — |
| Net current period other comprehensive income | 192 |
| Balance as of December 31, 2012 | $111 |

| | 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 that discovers and develops medicines in three product areas: complex generics, biosimilars and novel drugs. The three product areas correspond with their respective regulatory pathways. However the Company's portfolio of complex generics, biosimilars and novel drugs 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. All of the Company's revenues through December 31, 2013 have come from its collaborative partners and are based solely on activities in the United States.

**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, 2013 and December 31, 2012, 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, 2013 and December 31, 2012 are summarized as follows (in thousands):

| 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 | $— |

| Description | Balance as of December 31, 2012 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Other Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents | $ 47,940 | $47,940 | $ — | $— |
| Marketable securities: | | | | |
| U.S. Government-sponsored enterprise obligations | 51,225 | — | 51,225 | — |
| Corporate debt securities | 130,730 | — | 130,730 | — |
| Commercial paper obligations | 65,138 | — | 65,138 | — |
| Foreign government bonds | 40,520 | — | 40,520 | — |
| Total | $335,553 | $47,940 | $287,613 | $— |

For the years ended December 31, 2013 and 2012, 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, 2013 and December 31, 2012.

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

The following tables summarize the Company's cash, cash equivalents and marketable securities as of December 31, 2013 and December 31, 2012 (in thousands):

| 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 |

| As of December 31, 2012 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Cash and money market funds | $ 52,990 | $ — | $ — | $ 52,990 |
| U.S. Government-sponsored enterprise obligations | | | | |
| Due in one year or less | 6,000 | — | — | 6,000 |
| Due in two years or less | 45,195 | 30 | — | 45,225 |
| Corporate debt securities | | | | |
| Due in one year or less | 70,967 | 18 | (10) | 70,975 |
| Due in two years or less | 59,738 | 40 | (23) | 59,755 |
| Commercial paper obligations due in one year or less | 65,104 | 34 | — | 65,138 |
| Foreign government bonds | | | | |
| Due in one year or less | 12,923 | 1 | (1) | 12,923 |
| Due in two years or less | 27,575 | 32 | (10) | 27,597 |
| Total | $340,492 | $155 | $(44) | $340,603 |
| Reported as: | | | | |
| Cash and cash equivalents | $ 52,990 | $ — | $ — | $ 52,990 |
| Marketable securities | 287,502 | 155 | (44) | 287,613 |
| Total | $340,492 | $155 | $(44) | $340,603 |

At December 31, 2013 and December 31, 2012, the Company held 28 marketable securities that were in a continuous unrealized loss position for less than one year. At December 31, 2013 and

December 31, 2012, 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, 2013 and December 31, 2012 (in thousands):

| | As of December 31, 2013 | | As of December 31, 2012 | |
|---|---|---|---|---|
| | Aggregate Fair Value | Unrealized Losses | Aggregate Fair Value | Unrealized Losses |
| Corporate debt securities: | | | | |
| Due in one year or less | $38,508 | $(14) | $43,868 | $(10) |
| Due in two years or less | $11,696 | $ (7) | $28,484 | $(23) |
| Foreign government bonds: | | | | |
| Due in one year or less | $ 6,203 | $ (2) | $ 9,428 | $ (1) |
| Due in two years or less | $ — | $ — | $10,194 | $(10) |
| Asset-backed securities: | | | | |
| Due in one year or less | $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, 2013 and December 31, 2012, property and equipment, net consists of the following (in thousands):

| | 2013 | 2012 | Depreciable Lives |
|---|---|---|---|
| Computer equipment | $ 1,742 | $ 1,664 | 3 years |
| Software | 7,221 | 6,380 | 3 years |
| Office furniture and equipment | 2,379 | 2,201 | 5 to 6 years |
| Laboratory equipment | 35,919 | 31,128 | 7 years |
| Leasehold improvements | 11,350 | 8,677 | Shorter of asset life or lease term |
| Less: accumulated depreciation | (33,912) | (27,670) | |
| | $ 24,699 | $ 22,380 | |

During 2013 and 2012, the Company disposed of certain lab and computer equipment with total gross carrying amount of $66,000 and $186,000, respectively, and accumulated depreciation of $43,000 and $167,000, respectively. Depreciation and amortization expense, including amortization of assets recorded under capital leases (in 2011 only), amounted to $7.1 million, $6.4 million and $4.1 million for the years ended December 31, 2013, 2012 and 2011, respectively.

**6. Intangible Assets**

As of December 31, 2013 and December 31, 2012, intangible assets, net of accumulated amortization, are as follows (in thousands):

| | Weighted-Average Amortization Period (in years) | 2013 | | 2012 | |
|---|---|---|---|---|---|
| | | Gross Carrying Amount | Accumulated Amortization | Gross Carrying Amount | Accumulated Amortization |
| Core and developed technology . . | 10 | $10,257 | $(4,607) | $10,257 | $(3,546) |
| Non-compete agreement . . . . . | 2 | 170 | (170) | 170 | (170) |
| Total intangible assets . . . . . | 10 | $10,427 | $(4,777) | $10,427 | $(3,716) |

The Company's intangible assets are described within Note 16, *Parivid, LLC*.

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, $1.1 million and $1.4 million during years ended December 31, 2013, 2012 and 2011, respectively.

The Company expects to incur amortization expense of appropriately $1.1 million per year for each of the next five years.

**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. 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, 2013 and December 31, 2012, accrued expenses consisted of the following (in thousands):

| | 2013 | 2012 |
|---|---|---|
| Accrued compensation . . . . . | $ 6,696 | $5,322 |
| Accrued contracted research costs . . . . . | 2,480 | 2,619 |
| Accrued royalties . . . . . | 158 | 419 |
| Accrued professional fees . . . . . | 1,170 | 979 |
| Other . . . . . | 943 | 302 |
| | $11,447 | $9,641 |

**9. Collaborations and License Agreements**

***2003 Sandoz Collaboration***

In November 2003, the Company entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration, with Sandoz AG and Sandoz Inc. collectively, Sandoz, to jointly develop and commercialize Enoxaparin Sodium Injection, a generic version of Lovenox®, a low molecular weight heparin, or LMWH.

Under the 2003 Sandoz Collaboration, the Company granted Sandoz the exclusive right to manufacture, distribute and sell Enoxaparin Sodium Injection in the United States. The Company agreed to provide development and related services on a commercially reasonable basis, which included developing a manufacturing process to make Enoxaparin Sodium Injection, scaling up the process, contributing to the preparation of an Abbreviated New Drug Application, or ANDA, in Sandoz's name to be filed with the FDA, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee which is responsible for overseeing development, legal and commercial activities and which approves the annual collaboration plan. Sandoz is responsible for commercialization activities and will exclusively distribute and market the product. The Company identified two significant deliverables in this arrangement consisting of: (i) a 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.

In July 2010, the FDA granted marketing approval of the ANDA for Enoxaparin Sodium Injection filed by Sandoz. The Company is paid at cost for external costs incurred for development and related activities and is paid for full time equivalents, or FTEs, performing development and related services. The profit-share or royalties Sandoz is obligated to pay the Company under the 2003 Sandoz Collaboration differ depending 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 is one or more third-party which is not Sanofi-Aventis marketing a Lovenox-Equivalent Product. Until October 2011, no third-party competitors were marketing a Lovenox-Equivalent Product; therefore, Sandoz paid the Company 45% of the contractual profits from the sale of Enoxaparin Sodium Injection. Profits on sales of Enoxaparin Sodium Injection are calculated by deducting from net sales the cost of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. 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, which was achieved in December 2011, at which point the Company reverted back to receiving profit share revenue. Additionally, in October 2011, FDA approved the ANDA for the enoxaparin product of Actavis and Amphastar. In January 2012, following the Court of Appeals for the Federal Circuit granting a stay of the preliminary injunction previously issued against them by the United States District Court, Actavis announced that it and Amphastar intended to launch their enoxaparin product. Consequently, Sandoz is obligated to pay the Company a royalty on net sales in each post-launch contract year, which for net sales up to a pre-defined sales threshold is payable at a 10% rate, and for net sales above the sales threshold increases to 12%. During the year ended December 31, 2013, the Company earned royalties of $16.7 million on Sandoz's net sales of Enoxaparin Sodium Injection. During the years ended December 31, 2012 and 2011, the Company earned hybrid profit share/royalties of $54.8 million and $260.5 million, respectively, on Sandoz's net sales of Enoxaparin Sodium Injection.

If certain milestones were achieved with respect to Enoxaparin Sodium Injection under certain circumstances, Sandoz agreed to make payments to the Company which would reach $55 million. Under the 2003 Sandoz Collaboration, in July 2010, upon the achievement of a regulatory milestone the Company earned and recognized $5.0 million in research and development revenue. In addition, no third-party competitors had marketed a Lovenox-Equivalent Product as of July 2011, the one year anniversary of the FDA's approval of Enoxaparin Sodium Injection. As a result, in the year ended December 31, 2011, the Company earned and recognized $10.0 million in product revenue upon the achievement of the commercial milestone. 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.

A portion of the 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. Sandoz also may offset a portion of any product liability costs and certain other expenses arising from patent litigation against any profit-sharing amounts, royalties and milestone payments. 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 of $3.8 million, $3.9 million and $4.1 million, respectively, were recorded as a reduction in product revenue in the years ended December 31, 2013, 2012 and 2011, respectively.

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 manufacturing raw material purchases, which are recorded on a net basis as an offset to the related development expense. There have been no such manufacturing raw material purchases since 2006. Under the 2003 Sandoz Collaboration, the Company recorded research and development revenue of $3.0 million, $3.8 million and $6.4 million in the years ended December 31, 2013, 2012 and 2011, respectively.

***2006 Sandoz Collaboration***

In July 2006, the Company entered into a Stock Purchase Agreement and an Investor Rights Agreement with Novartis Pharma AG, and in June 2007, the Company and Sandoz AG executed a collaboration and license agreement, as amended, or the Second Sandoz Collaboration Agreement, related to the development and commercialization of M356, which is designed to be a generic version of Copaxone® (glatiramer acetate injection). Together, this series of agreements is referred to as the "2006 Sandoz Collaboration."

Pursuant to the terms of the Stock Purchase Agreement, the Company sold 4,708,679 shares of common stock to Novartis Pharma AG, an affiliate of Sandoz 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 is being recognized in revenue on a straight-line basis over the estimated development period of approximately seven years beginning in June 2007. The Company recognized research and development revenue relating to this paid premium of approximately $1.1 million, $2.2 million and $2.2 million in the years ended December 31, 2013, 2012 and 2011, respectively. The portion of the equity premium that is unearned at December 31, 2013 is included in deferred revenue in the consolidated balance sheets.

Under the 2006 Sandoz Collaboration, the Company and Sandoz AG expanded the geographic markets for Enoxaparin Sodium Injection covered by the 2003 Sandoz Collaboration to include the European Union and further agreed to exclusively collaborate on the development and commercialization of M356 for sale in specified regions of the world. 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. The Company has agreed to provide development and related services 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. The Company has the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and which approves the annual collaboration plan. Sandoz AG is responsible for commercialization activities and will exclusively distribute and market any products covered by the 2006 Sandoz Collaboration. The Company identified two significant deliverables in this arrangement consisting of (i) a license and (ii) the development and related services. The Company determined that the license did not meet the criteria for separation as it does not have stand-alone value apart from the development services, which are proprietary to the Company. Therefore, the Company has determined that a single unit of accounting exists with respect to the 2006 Sandoz Collaboration.

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. 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.

Costs, including development costs and the cost of clinical studies, will be borne by the parties in varying proportions, depending on the type of expense and the related product. All commercialization responsibilities and costs will be borne by Sandoz AG. Under the 2006 Sandoz Collaboration, the Company is paid at cost for any external costs incurred in the development of products where development activities are funded solely by Sandoz AG or partly in proportion where development costs are shared between the Company and Sandoz AG. The Company also is paid at a contractually specified rate for FTEs performing development services where development activities are funded solely by Sandoz AG or partly by proportion where development costs are shared between the Company and Sandoz AG. Upon commercialization, the Company will earn a 50% 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. Additionally, 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 the products under the collaboration, which include: a $10.0 million regulatory milestone payment related to the approval by the FDA of M356, and $153.0 million in sales-based and commercial milestone payments, of which up to $140.0 million (including the M356 regulatory milestone) are U.S.-based milestones. The Company has concluded that the regulatory milestone pursuant to its 2006 Sandoz Collaboration is substantive. The Company evaluated factors such as the scientific and regulatory risks that must be overcome to achieve the respective milestone, 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 regulatory milestone are recognized as research and development revenue upon successful accomplishment of the milestone. 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. The Company has not earned and therefore has not recognized any milestone payments under this arrangement.

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. Under the 2006 Sandoz Collaboration, the Company recorded research and development revenue of $1.3 million, $1.0 million and $5.5 million in the years ended December 31, 2013, 2012 and 2011, respectively. The Company recorded a reduction in research and development revenue for shared development costs of $0.6 million, $0.7 million and $1.5 million for the years ended December 31, 2013, 2012 and 2011, respectively.

***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 biosimilar product candidates. The Company refers to this agreement as the "Baxter Agreement." The Baxter Agreement became effective in February 2012.

Under the Baxter Agreement, the Company agreed to collaborate, on a world-wide basis, on the development and commercialization of two biosimilar products, M923 and M834, indicated in the inflammatory and autoimmune therapeutic areas, or the initial products. In July 2012, Baxter selected a third product for inclusion in the collaboration, a monoclonal antibody for oncology which has been designated as M511. On December 19, 2013, Baxter terminated its option to license M511 under the Baxter Agreement following an internal portfolio review. The Company and Baxter are continuing to collaborate on M923 and M834 and evaluate additional products for development. The Company continues to develop M511 as part of its biosimilars business. Baxter has the right, until February 2015, to select up to three additional biosimilars to be included in the collaboration. Momenta may also consent, at its option, to allow Baxter to name a replacement product for M511, if Baxter requests such replacement.

The process for achieving milestones under the Baxter Agreement is as follows:

- Baxter selects an additional product to the collaboration and the Company initiates development.
- If the Company achieves pre-defined "minimum development" criteria related to the additional product, Baxter is given an option to exercise exclusive license rights.
- If Baxter exercises its exclusive license option to advance the additional product under the Baxter Agreement, the Company will earn a license payment.
- If the Company achieves pre-defined "technical development" criteria related to an initial product or additional product, the Company will earn a milestone payment.
- For an initial and additional product, if the Company either (a) submits an Investigational New Drug application, or IND, to the FDA or equivalent application in the European Union (b) is not required to file an IND, either referred to as the "Transition Period," the Company will earn a milestone payment.
- Following the Transition Period, Baxter will assume responsibility for development of each biosimilar, and the Company has the potential to receive up to $250 million in regulatory milestone payments. These milestones are designed to reward the Company, on a sliding scale, for reducing the scope of the clinical activities required to develop each biosimilar.

Under the Baxter Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize designated products for all therapeutic indications. The Company has agreed to provide development and related services on a commercially reasonable basis through the Transition Period for each product, 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 any products covered by the Baxter Agreement. 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 products 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 has the option to participate, at its discretion, in a cost and profit share arrangement for the four additional products up to 30%. If the profit share is elected, the royalties payable would be reduced by up to nearly half. Absent a cost share arrangement, 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.

In addition, the Company has agreed, for a period commencing six months following the effective date and ending on the earlier of (i) three years from the effective date of the Baxter Agreement (subject to certain limited time extensions as provided for in the Baxter Agreement) or (ii) the selection of the four additional products, to notify Baxter of bona fide offers from third parties to develop or commercialize a biosimilar that could be an additional product candidate. Following such notification, if Baxter does not select such proposed product or products for inclusion in the collaboration, the Company has the right to develop, manufacture, and commercialize such product or products on its own or with a third party. The Company also agreed to provide Baxter with a right of first negotiation with respect to collaborating in the development of a competing product 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. Following the third anniversary of the effective date of the Baxter Agreement (subject to certain limited time extensions as provided for in the Baxter Agreement), the Company may develop, on its own or with a third party, any biosimilar product not named under the Baxter Agreement, subject to certain restrictions.

Under the terms of the Baxter Agreement, the Company received an initial cash payment of $33.0 million. The Company is eligible to receive from Baxter license payments totaling $21.0 million for the exercise of options with respect to the additional three product candidates that can be named under the Baxter Agreement, payments of $5.0 million each for extensions of the period during which such additional products may be selected, and a license payment of $7.0 million upon the achievement of pre-defined "minimum development" criteria, as defined in the agreement, for M834 (a selected biosimilar). The Company is also eligible to receive from Baxter an aggregate of approximately $316.0 million in potential milestone payments, comprised of (i) up to $66.0 million in substantive milestone payments upon achievement of specified technical and development milestone events across the five product candidates, and (ii) regulatory milestone payments totaling up to $250.0 million, on a sliding scale, across the five product candidates where, based on the products' regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval. The Company is no longer eligible to receive the following payments associated with M511: $7.0 million option payment; $14.0 million in technical and development milestone payments; and $50.0 million in regulatory milestone payments. Two of the technical and development milestones were time-based and the total eligible milestones have been adjusted to correspond to current development

plans. There are no other time-based milestones included in the Baxter Agreement. The technical and development milestones include (i) achievement of certain criteria that will ultimately drive commercial feasibility for manufacturing the products and (ii) acceptance by the FDA of an IND or acceptance in the European Union of an equivalent application.

The Company continues to advance toward achievement of defined milestones in 2014 for its two biosimilar products under development with Baxter. For its lead biosimilar M923, the $12.0 million in milestones targeted for second half of 2014 are achievement of technical development criteria and the submission of a regulatory application in the European Union. The achievement of pre-defined "minimum development" criteria would generate a $7.0 million milestone payment for M834 in 2014.

In addition, if any of the five products are 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 each 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 the products, on a product-by-product and country-by-country basis, until there is no remaining payment obligation with respect to a 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;
- the Company in the event Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products within a certain time period;
- Baxter for its convenience; or
- the Company in the event Baxter does not exercise commercially reasonable efforts to commercialize a product in the United States or other specified countries, provided that we also have certain rights to directly commercialize such product, 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 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 million, which included the $33 million upfront payment and aggregate option payments for the four additional biosimilars of $28 million, was allocated to the units of accounting based on the relative selling price method. Of the $61 million, $10.3 million was allocated to the first initial 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 has been allocated to the second initial 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. On December 19, 2013, Baxter terminated its option to license M511, a named product under the Baxter Agreement. Accordingly, the expected consideration to be received under the arrangement has been reduced by $7 million (M511 option payment) and there is now one less deliverable. The Company determined that the change in expected consideration to be received under the arrangement represents a change in estimate and, as a result, the Company reallocated the revised expected consideration of $54 million to the remaining deliverables under the agreement using the original BESP. The Company will recognize the resulting change in revenue on a prospective basis. Of the $54 million, $11 million was allocated to the first initial product license together with the related research and development services, $11 million to each of the three additional product licenses with the related research and development services, $10 million has been allocated to the second initial 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.

The Company will commence revenue recognition for each of the five units of accounting related to the products upon delivery of the related development and product license and will record this revenue on a straight-line basis over the applicable performance period during which the research and development services will be delivered. The Company will recognize the revenue related to the joint steering committee deliverable over the applicable performance period during which the research and development services will be delivered. The Company has determined that the performance period for each of the combined five units of accounting consisting of the products and related research and development services, begins upon delivery of the related development and product license and ends upon FDA approval of the related product. The Company has also determined that the applicable performance period for the joint steering committee deliverable begins upon delivery of the first development and product license and ends upon the latest date of FDA approval. The Company currently estimates that the performance period for the two initial products, considering their respective stage of development, is approximately five and eight years, respectively, and the period of performance for the joint steering committee is approximately eleven years.

In 2012, the Company commenced recognition of the revenue allocated to the two initial products but not for the three additional products as those licenses have not been delivered. The Company recognized revenue relating to the amortized portion of the upfront payment of $2.9 million and $3.0 million in the years ended December 31, 2013 and 2012, respectively. The portion of the upfront payment that is unearned at December 31, 2013 is included in deferred revenue.

The Company recognizes research and development revenue from FTE services and research and development revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs is recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such development and related services. Beginning in 2013, the Company commenced billing to Baxter FTE fees and external development costs for reimbursable activities related to one of the biosimilars in development. For the year ended December 31, 2013, the Company recorded research and development revenue of $11.0 million for reimbursement from Baxter for research and development services and external development costs incurred in connection with the Baxter Agreement.

Any associated royalty or profit sharing payments will be considered contingent fees that will be recorded as earned in future periods. Baxter's option to extend the naming period is considered to be substantive. As such, potential fees associated with the naming period extensions will be recognized in future periods if and when Baxter exercises its right to extend the naming period for any additional products.

The Company has concluded that certain of the technical and development milestones and all of the regulatory 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 non-refundable technical, development and regulatory milestones will be recognized upon successful accomplishment of the milestones as research and development revenue. The Company has not earned and therefore has not recognized any milestone payments under this arrangement.

***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, 2013, 2012 and 2011 (in thousands):

| | 2013 | 2012 | 2011 |
|---|---|---|---|
| License maintenance fees | $ 82 | $ 183 | $ 158 |
| Royalties | 252 | 1,013 | 6,563 |
| Total | $334 | $1,196 | $6,721 |

Beginning in 2013, 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 annual license payment for 2013 was applied against cumulative royalties due for the year ended December 31, 2013.

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 and, 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.

The Company previously had an exclusive patent license agreement dated October 31, 2002 with M.I.T granting the Company various licenses under certain patents solely related to the commercial sale or leasing of sequencing machines, including the performance of sequencing services. The Company terminated that agreement in January 2013. Nothing in the notice of termination impacts the agreement between the Company and M.I.T dated November 1, 2002.

**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, 2013 and 2012, 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***

On March 5, 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 shareholder 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.

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).

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 (in thousands):

| | Shares Available for Issuance |
|---|---|
| Shares reserved for issuance at June 11, 2013 | 3,300 |
| Add: stock options and restricted stock awards forfeited or expired under prior plans | 68 |
| Less: stock options and awards granted from June 12, 2013 to December 31, 2013 | (321) |
| Shares reserved for issuance at December 31, 2013 | 3,047 |

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 at 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 may be granted to employees, consultants and members of the Company's board of directors. 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. Restricted stock awards generally vest ratably over four years.

***Share-Based Compensation***

Total compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the Company's employee stock purchase plan for the years ended December 31, 2013, 2012 and 2011 was $12.8 million, $13.7 million and $11.1 million, respectively.

Share-based compensation expense related to outstanding employee stock option grants was $8.0 million, $7.3 million and $6.2 million for the years ended December 31, 2013, 2012 and 2011, respectively.

During the year ended December 31, 2013, the Company granted 1,436,446 stock options, of which 1,025,771 were granted in connection with annual merit awards, 268,675 were granted to new hires, and 142,000 were granted to members of the Company's Board of Directors. 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 | | |
| | 2013 | 2012 | 2011 | 2013 | 2012 | 2011 |
| Expected volatility | 63% | 66% | 68% | 64% | 66% | 75% |
| Expected dividends | — | — | — | — | — | — |
| Expected life (years) | 6.0 | 6.3 | 6.3 | 0.5 | 0.5 | 0.5 |
| Risk-free interest rate | 1.5% | 1.3% | 2.7% | 0.1% | 0.1% | 0.2% |

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

| | 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, 2013 | 5,386 | $13.48 | | |
| Granted | 1,436 | 13.20 | | |
| Exercised | (436) | 9.53 | | |
| Forfeited | (104) | 14.05 | | |
| Expired | (43) | 14.87 | | |
| Outstanding at December 31, 2013 | 6,239 | $13.67 | 6.24 | $26,307 |
| Exercisable at December 31, 2013 | 4,303 | $13.59 | 5.14 | $18,894 |
| Vested or expected to vest at December 31, 2013 | 6,036 | $13.67 | 6.14 | $25,505 |

The weighted average grant date fair value of option awards granted during 2013, 2012 and 2011 was $7.62, $9.16 and $9.27 per option, respectively. The total intrinsic value of options exercised during 2013, 2012 and 2011 was $2.7 million, $1.6 million and $4.3 million, respectively. At December 31, 2013, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $12.8 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.5 years. The total fair value of options vested during 2013, 2012 and 2011 was $8.3 million, $7.4 million and $6.4 million, respectively.

Cash received from option exercises for 2013, 2012 and 2011 was $4.2 million, $1.5 million and $5.0 million, respectively.

***Restricted Stock Awards***

The Company has also made awards of restricted common stock to employees, officers and directors. During the year ended December 31, 2013, the Company awarded 140,300 shares of time-based restricted common stock to its officers in connection with its annual merit grant, 30,000 shares of time-based restricted common stock to newly hired employees and 1,680 shares of performance-based restricted common stock to a newly hired employee. The time-based restricted common stock fully vests over the four years following the grant date. The performance condition that triggers vesting of the performance-based awards is the approval in the United States from the FDA for M356, the Company's second major generic program, provided that approval occurs on or before March 28, 2015. The Company has granted 949,620 shares of restricted common stock tied to this M356 performance condition to its employees and officers. The awards of restricted common stock are generally forfeited if the employment relationship terminates with the Company prior to vesting.

The Company recorded share-based compensation expense related to outstanding restricted stock awards, including the performance-based shares because the Company determined that it was probable the performance condition would be achieved, of $4.3 million, $6.0 million and $4.4 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $5.7 million, which is expected to be recognized over the weighted average remaining requisite service period of approximately 1 year.

A summary of the status of nonvested shares of restricted stock as of December 31, 2013, 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, 2013 | 1,137 | $14.61 |
| Granted | 171 | 13.26 |
| Vested | (134) | 14.55 |
| Cancelled | (40) | 14.61 |
| Nonvested at December 31, 2013 | 1,134 | $14.41 |

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of December 31, 2013 are summarized below (in thousands):

| Vesting Schedule | Nonvested Shares |
|---|---|
| Time-based | 297 |
| Performance-based | 837 |
| Nonvested at December 31, 2013 | 1,134 |

The total fair value of shares of restricted stock vested during 2013, 2012 and 2011 was $2.0 million, $1.8 million and $1.7 million, respectively.

***Employee Stock Purchase Plan***

Under the 2004 Employee Stock Purchase Plan, or 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 plan periods begin on February 1 and August 1 of each year. The ESPP provides for the issuance of up to 524,652 shares of common stock to participating employees. At December 31, 2013, the Company had 95,594 shares available for grant under the ESPP. The Company issued 80,219 shares of common stock to employees under the plan during the year ended December 31, 2013. The fair value of each ESPP award was 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 are noted in the table above. 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. During each of the years ended December 31, 2013, 2012 and 2011, the Company recorded ESPP share-based compensation expense of $0.4 million, $0.3 million and $0.3 million, respectively. At December 31, 2013, subscriptions were outstanding for an estimated 38,091 shares at a fair value of approximately $5.49 per share. The weighted average grant date fair value of the offerings during 2013, 2012 and 2011 was $4.73, $5.17 and

$5.80 per share, respectively. Cash received from the ESPP for 2013, 2012 and 2011 was $0.9 million, $0.7 million and $0.6 million, respectively.

**12. Net (Loss) Income Per Common Share**

The following table sets forth the Company's reconciliation of basic and diluted share amounts for the years ended December 31, 2013, 2012 and 2011 (in thousands, except per share amounts):

| | 2013 | 2012 | 2011 |
|---|---|---|---|
| Numerator: | | | |
| Net (loss) income | $(108,408) | $(58,648) | $180,356 |
| Denominator: | | | |
| Basic weighted average common shares outstanding | 50,907 | 50,411 | 49,852 |
| Weighted average common stock equivalents from assumed exercise of stock options and restricted stock awards | — | — | 971 |
| Diluted weighted average common shares outstanding | 50,907 | 50,411 | 50,823 |
| Basic net (loss) income per common share | $ (2.13) | $ (1.16) | $ 3.62 |
| Diluted net (loss) income per common share | $ (2.13) | $ (1.16) | $ 3.55 |
| Weighted-average anti-dilutive shares related to: | | | |
| Outstanding stock options | 4,492 | 3,815 | 2,062 |
| Restricted stock awards | 929 | 1,075 | 629 |

For the years ended December 31, 2013 and 2012, the effect of all potentially dilutive securities is anti-dilutive as the Company had a net loss during those periods. Accordingly, basic and diluted net loss per share is the same in the years ended December 31, 2013 and 2012.

The weighted-average anti-dilutive shares shown in the foregoing table were not included in the computation of diluted net (loss) income per share. In the period in which the Company reported net income, anti-dilutive shares comprise those common stock equivalents that have either an exercise price above the average stock price for the period or average unrecognized share-based compensation expense related to the common stock equivalents that are sufficient to "buy back" the entire amount of shares. In the periods in which the Company had a net loss, anti-dilutive shares comprise the impact of that 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 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, 2013.

**13. Income Taxes**

A reconciliation of the federal statutory income tax provision to the Company's actual provision for the years ended December 31, 2013, 2012 and 2011 is as follows (in thousands):

| | 2013 | 2012 | 2011 |
|---|---|---|---|
| (Benefit) provision at federal statutory tax rate | $(36,856) | $(19,931) | $ 61,324 |
| State taxes, net of federal benefit | (5,724) | (3,095) | 9,821 |
| Share-based compensation | 2,106 | 2,655 | 1,826 |
| Tax credits | (2,404) | — | (643) |
| Other | 15 | 14 | 36 |
| Change in valuation allowance | 42,863 | 20,357 | (72,364) |
| 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 available federal net operating loss carryforwards to offset this income. At December 31, 2013, the Company had federal and state net operating loss carryforwards of $142.4 million and $135.8 million, respectively, available to reduce future taxable income and which will expire at various dates through 2033. Of this amount, approximately $13.1 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, 2013, the Company had federal and state research and development and other credit carryforwards of $11.3 million and $5.2 million, respectively, available to reduce future tax liabilities. The federal and state research and development credit carryforwards will expire at various dates beginning in 2024 through 2033 and 2019 through 2028, respectively. Ownership changes, as defined in Tax Reform Act of 1986, in future periods may place limits on the Company's ability to utilize its net operating loss carryforwards and tax credit carryforwards. The Company has an ongoing research and development credit study that has not yet been completed as of the date of this filing. As the Company has a full valuation allowance on its net deferred tax assets, there will be no financial statement impact for any differences between the credits claimed on its tax returns versus credits substantiated as part of the study.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax

purposes. Significant components of the Company's deferred tax assets for the years ended December 31, 2013 and 2012 are as follows (in thousands):

| | 2013 | 2012 |
|---|---|---|
| Deferred tax assets: | | |
| Federal and state net operating losses | $ 50,414 | $ 11,119 |
| Research credits | 10,466 | 7,917 |
| Deferred compensation | 12,708 | 11,271 |
| Deferred revenue | 10,887 | 12,450 |
| Accrued expenses | 2,890 | 1,780 |
| Intangibles | 2,310 | 2,369 |
| Depreciation | 819 | 894 |
| Total deferred tax assets | 90,494 | 47,800 |
| Deferred tax liabilities: | | |
| Unrealized gain on marketable securities | (9) | (39) |
| Total deferred tax liabilities | (9) | (39) |
| Valuation allowance | (90,485) | (47,761) |
| Net deferred tax assets | $ — | $ — |

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $42.7 million for the year ended December 31, 2013, primarily as a result of the current period net loss.

In July 2013, the FASB issued ASU No. 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. ASU No. 2013-11 provides guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. ASU No. 2013-11 states that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, except as follows. To the extent a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. The assessment of whether a deferred tax asset is available is based on the unrecognized tax benefit and deferred tax asset that exist at the reporting date and should be made presuming disallowance of the tax position at the reporting date. ASU No. 2013-11 will be applied prospectively to all unrecognized tax benefits that exist at the effective date for public entities for fiscal years (and interim reporting periods within those years) beginning after December 15, 2013. The Company does not anticipate the adoption of this ASU will have a material impact on its financial condition or results of operations.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for the years ended December 31, 2013 and 2012 is as follows (in thousands):

| | 2013 | 2012 |
|---|---|---|
| Balance, beginning of year | $2,897 | $2,825 |
| Additions for tax positions related to the current year | 1,568 | 72 |
| Reductions of tax positions of prior years | — | — |
| Balance, end of year | $4,465 | $2,897 |

As of December 31, 2013 and 2012, the Company had $4.5 million and $2.9 million of gross unrecognized tax benefits, respectively, of which $4.3 million and $2.8 million, respectively, if recognized, would not impact the Company's effective tax rate as there is a full valuation allowance on these credits.

The Company'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 2010, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2010. As of December 31, 2013, the Company was not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

**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 $12.8 million, $10.0 million and $6.9 million for the years ended December 31, 2013, 2012 and 2011, respectively.

In September 2004, the Company entered into an agreement with Vertex Pharmaceuticals 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, or on such other earlier date as provided in accordance with the West Kendall Sublease. 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 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 will be 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 certain improvements that the Company will construct to the leased office and laboratory space. During the year ended December 31, 2013, the Company constructed certain improvements to its leased office and laboratory space, paid its subcontractors and was subsequently reimbursed by BMR. The Company then recorded short and long-term liabilities for the construction allowance in its consolidated balance sheet. The Company will amortize the construction allowance 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.

There are no future minimum capital lease commitments as the Company repaid all borrowings under its Master Lease Agreement with General Electric Capital Corporation during 2011. Total operating lease commitments as of December 31, 2013 are as follows (in thousands):

| | Operating Leases |
|---|---|
| 2014 | $10,986 |
| 2015 | 7,898 |
| 2016 | 4,301 |
| 2017 | 83 |
| 2018 and beyond | — |
| Total future minimum lease payments | $23,268 |

***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. Beginning in 2014, 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***

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 M356. The suit alleged infringement related to four of the seven Orange Book patents listed 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 Company 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 the present 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 patents listed 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. The Orange Book patents and one non-Orange book patent expire in May 2014 and one non-Orange Book patent expires in September 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35 U.S.C. section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz or Mylan ANDA prior to the expiration of the Orange Book patents. 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 patents, including the one patent set to expire in 2015. Several patents expiring in May 2014 remain in force. 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 on October 18, 2013 the CAFC denied the petition. Teva filed a petition for review by the Supreme Court in January 2014.

On December 10, 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and the Company for patent infringement related to certain other non-Orange Book patents seeking declaratory and injunctive relief that would prohibit the launch of the Company's product until the last to expire of these patents as well as damages in the event that Sandoz has launched the product. In January 2010, the Company and Sandoz filed a motion to dismiss this second suit on several grounds and in July 2013, the motion to dismiss the suit was granted.

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 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 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 request.

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 has filed a notice of appeal of that decision to the CAFC. 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

$0.8 million, $0.7 million and $0.5 million of such match expense in the years ended December 31, 2013, 2012 and 2011, respectively.

**16. Parivid, LLC**

In April 2007, the Company entered into an asset purchase agreement, or the Purchase Agreement, with Parivid, LLC, or Parivid, a provider of data integration and analysis services to the Company, and S. Raguram, the principal owner and Chief Technology Officer of Parivid. Parivid was considered to be a related party because a co-founder and member of the Company's Board of Directors is the brother of S. Raguram. Pursuant to the Purchase Agreement, the Company acquired patent rights, software, know-how and other intangible assets, and assumed certain specified 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 (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 2007, the Company recorded a total purchase price of $4.5 million that includes the $2.5 million cash paid at the closing and $2.0 million in Initial Milestone payments, which were probable and accrued at the time.

In August 2009, the Company entered into an Amendment to the Purchase Agreement where the Company 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 the Company's common stock, at a value of $10.92 per share. In addition, in September 2009, the Company 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, the Company entered into an Amendment to the Purchase Agreement where the parties agreed that a milestone payment would be made in cash rather than through the issuance of Company stock. In August 2011, the Company 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 the Enoxaparin Sodium Injection developed technology that was achieved in July 2011. The Company capitalized the payment as developed technology, which is included in intangible assets in the consolidated balance sheets. The developed technology is being amortized over the estimated useful life of the Enoxaparin Sodium Injection developed technology of approximately 10 years.

**17. Tax Incentive Agreement**

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, 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 maintained it in 2013, 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, 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.

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

| | Quarter Ended | | | |
|---|---|---|---|---|
| **(in thousands, except per share data)** | **March 31** | **June 30** | **September 30** | **December 31** |
| **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 |
| **2012** | | | | |
| Product revenue | $ 22,029 | $ 19,352 | $ 2,579 | $ 10,812 |
| Research and development revenue | $ 2,199 | $ 2,511 | $ 2,523 | $ 1,916 |
| Total collaboration revenue | $ 24,228 | $ 21,863 | $ 5,102 | $ 12,728 |
| Net loss | $ (4,982) | $(10,166) | $(25,822) | $(17,677) |
| Comprehensive loss | $ (4,875) | $(10,206) | $(25,637) | $(17,737) |
| Basic and diluted net loss per common share | $ (0.10) | $ (0.20) | $ (0.51) | $ (0.35) |
| Shares used in computing basic and diluted net loss per common share | 50,240 | 50,354 | 50,500 | 50,547 |

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's issuing shares of its common stock during the year.

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

Not applicable.

## Item 9A. CONTROLS AND PROCEDURES

### 1. 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 of December 31, 2013. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934 is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. 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, 2013, our disclosure controls and procedures were effective at the reasonable assurance level.

### 2. Internal Control Over Financial Reporting

(a) Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, 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 and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- 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
- 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. 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.

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, 2013. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 1992 framework entitled "Internal Control—Integrated Framework." In May 2013, COSO issued an updated Internal Control-Integrated Framework, or the 2013 framework. Management continued to apply the 1992 framework in its 2013 assessment of internal controls and expects to adopt the 2013 framework during fiscal year 2014.

Based on its assessment, our management has concluded that, as of December 31, 2013, our internal control over financial reporting is effective based on those criteria.

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.

(b) Attestation Report of the Independent Registered Public Accounting Firm

**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, 2013, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 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, 2013, 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, 2013 and 2012, and the related consolidated statements of comprehensive (loss) income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013 of Momenta Pharmaceuticals, Inc. and our report dated February 28, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 28, 2014

(c) Changes in Internal Control Over Financial Reporting

None

**Item 9B. OTHER INFORMATION**

Not applicable.

## 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," "Corporate Governance—Our Executive Officers," "Corporate Governance—Section 16(a) Beneficial Ownership Reporting Compliance" and "Corporate Governance—Board Committees" in our definitive proxy statement for the 2014 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 the 2014 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 the 2014 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 the 2014 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 "Corporate Governance—Board Determination of Independence" in our definitive proxy statement for the 2014 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 Selection of Independent Registered Public Accounting Firm" in our definitive proxy statement for the 2014 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 28, 2014

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<br>Craig A. Wheeler | President, Chief Executive Officer and Director (Principal Executive Officer) | February 28, 2014 |
| /s/ RICHARD P. SHEA<br>Richard P. Shea | Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer) | February 28, 2014 |
| /s/ JAMES SULAT<br>James Sulat | Chairman of the Board and Director | February 28, 2014 |
| John K. Clarke | Director | February 28, 2014 |
| /s/ MARSHA H. FANUCCI<br>Marsha H. Fanucci | Director | February 28, 2014 |
| /s/ PETER BARTON HUTT<br>Peter Barton Hutt | Director | February 28, 2014 |
| /s/ BRUCE DOWNEY<br>Bruce Downey | Director | February 28, 2014 |
| /s/ THOMAS KOESTLER<br>Thomas Koestler | Director | February 28, 2014 |
| /s/ BENNETT M. SHAPIRO<br>Bennett M. Shapiro | Director | February 28, 2014 |
| /s/ ELIZABETH STONER<br>Elizabeth Stoner | Director | February 28, 2014 |

## 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 |
| 3.3 | Second Amended and Restated By-Laws | S-1 | 3.4 | 3/11/2004 | 333-113522 |
| | ***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 |
| 10.3† | Letter Agreement Regarding November 1, 2002 M.I.T. License, dated August 4, 2006, between the Massachusetts Institute of Technology and the Registrant | 8-K | 10.1 | 8/15/2006 | 000-50797 |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 10.4† | 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 |
| 10.5† | 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 |
| 10.6† | 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 |
| 10.7 | 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 |
| 10.8 | Letter Agreement dated January 29, 2007 between Sandoz AG and the Registrant | 10-K | 10.16 | 3/15/2007 | 000-50797 |
| 10.9 | Letter Agreement dated February 1, 2007 between Sandoz AG and the Registrant | 10-Q | 10.2 | 5/10/2007 | 000-50797 |
| 10.10 | 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 |
| 10.11† | 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 |
| 10.12 | 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 |
| 10.13 | 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 |
| 10.14† | 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 |
| 10.15† | 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 |
| 10.16 | Letter Agreement dated November 8, 2011 by and between the Registrant, Sandoz AG and Sandoz Inc. | 10-K | 10.20 | 2/28/2012 | 000-50797 |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 10.17† | Development, License and Option Agreement by and between the Registrant and Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA dated December 22, 2011 | 10-K | 10.21 | 2/28/2012 | 000-50797 |
| 10.18 | 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 |
| | ***Material Contracts—Management Contracts and Compensation Plans*** | | | | |
| 10.19# | Amended and Restated 2002 Stock Incentive Plan | 10-K | 10.17 | 3/15/2007 | 000-50797 |
| 10.20# | 2004 Stock Incentive Plan, as amended | 10-K | 10.18 | 3/15/2007 | 000-50797 |
| 10.21# | Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan | 10-Q | 10.1 | 8/16/2004 | 000-50797 |
| 10.22# | Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan | 10-Q | 10.2 | 8/16/2004 | 000-50797 |
| 10.23# | Form of Restricted Stock Agreement Under 2004 Stock Incentive Plan | 8-K | 10.2 | 2/28/2008 | 000-50797 |
| 10.24# | 2004 Employee Stock Purchase Plan | 10-Q | 10.1 | 5/6/2010 | 000-50797 |
| 10.25# | Non-Employee Director Compensation Summary | 10-Q | 10.3 | 8/5/2011 | 000-50797 |
| 10.26# | Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant | 10-Q | 10.7 | 11/8/2006 | 000-50797 |
| 10.27# | 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 |
| 10.28# | Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant | 10-Q | 10.8 | 11/8/2006 | 000-50797 |
| 10.29# | Nonstatutory Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant | 10-Q | 10.9 | 11/8/2006 | 000-50797 |
| 10.30# | Incentive Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant | 10-Q | 10.10 | 11/8/2006 | 000-50797 |
| 10.31# | Restricted Stock Agreement, dated December 15, 2006, between John E. Bishop and the Registrant | 10-K | 10.56 | 3/15/2007 | 000-50797 |
| 10.32# | Restricted Stock Agreement, dated December 14, 2007, between John E. Bishop and the Registrant | 10-K | 10.35 | 3/10/2008 | 000-50797 |
| 10.33# | Restricted Stock Agreement, dated August 15, 2007, between Richard P. Shea and the Registrant | 10-Q | 10.1 | 11/08/2007 | 000-50797 |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 10.34# | Form of Employment Agreement for executive officers | 10-Q | 10.3 | 5/9/2008 | 000-50797 |
| 10.35# | 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 |
| 10.36# | 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 |
| 10.37# | Form of Amendment to the Employment Agreement for executive officers dated December 15, 2010 | 10-K | 10.39 | 3/10/2011 | 000-50797 |
| 10.38# | 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 |
| 10.39# | Form of Restricted Stock Agreement | 8-K | 10.1 | 4/1/2011 | 000-50797 |
| *10.40# | Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan | | | | |
| 10.41# | Form of Stock Option Agreement under the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan | 8-K | 10.1 | 6/13/2013 | 000-50797 |
| 10.42# | 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*** | | | | |
| 10.43† | Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant | 10-Q | 10.9 | 11/12/2004 | 000-50797 |
| 10.44 | 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 |
| 10.45 | 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 |
| 10.46 | 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 |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to | | |
|---|---|---|---|---|---|
| | | | Exhibit No. | Filing Date with SEC | SEC File Number |
| 10.47 | 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 |
| 10.48 | 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 |
| 10.49 | First Amendment dated March 21, 2013 to the Sublease Agreement dated February 5, 2013 by and between BMR-Rogers Street LLC and the Registrant | 10-Q | 10.2 | 5/10/2013 | 000-50797 |
| 10.50 | 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*** | | | | |
| 10.51 | 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*** | | | | |
| 10.52 | 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 |
| 10.53 | 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 |
| 10.54 | 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 |
| 10.55† | Asset Purchase Agreement dated December 2, 2011 between the Registrant and Virdante Pharmaceuticals, Inc. | 10-K | 10.54 | 2/28/2012 | 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 | | | | |

| Exhibit Number | Description | Form or Schedule | Incorporated by Reference to Exhibit No. | Filing Date with SEC | SEC File Number |
|---|---|---|---|---|---|
| *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.** | | | | |
| 101.REF | XBRL Taxonomy Reference Linkbase Document.** | | | | |

* Filed herewith.

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

# Management contract or compensatory plan or arrangement filed as an Exhibit to this report pursuant to 15(a) and 15(c) of Form 10-K.

** submitted electronically herewith

The following financial information from Momenta Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the period ended December 31, 2013, filed with the SEC on February 28, 2014, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Comprehensive (Loss) Income for the years ended December 31, 2013, 2012, and 2011, (ii) the Consolidated Balance Sheets as of December 31, 2013 and 2012, (iii) the Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012, and 2011, (iv) the Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013, 2012, and 2011 and (v) Notes to Consolidated Financial Statements.