MOMENTA PHARMACEUTICALS INC
Form 10-K
February 28, 2012

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

Or

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

For the transition period from to
Commission file number: 000-50797

MOMENTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

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 o No ý

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

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 ý No o

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 ý No o

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

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 ý	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on June 30, 2011, based on $19.46 per share, the last reported sale price of Common Stock on the Nasdaq Global Market on that date, was $968,908,632.

As of February 15, 2012, the registrant had 51,334,554 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 2012 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

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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 specializing in the structural characterization, process engineering and biologic systems analysis of complex molecules, such as polysaccharides, polypeptides, and biologics (including proteins and antibodies). Our initial technology was built on the ability to characterize complex polysaccharides. Over the last decade, we have expanded our expertise into technologies that enable us to develop a diversified product portfolio of complex generic, follow-on biologic, and novel therapeutics. Our business strategy has been to develop both generic and novel therapeutics, and we are working with collaborative partners to develop and commercialize our complex generics and follow-on biologics. This strategy was validated by the marketing approval and commercial launch of enoxaparin sodium injection, a generic version of Lovenox®, in July 2010. Since its launch through December 31, 2011, we have recorded enoxaparin sodium injection product revenues totaling $357 million, driven primarily by its initial status as a sole generic. We believe that our scientific capabilities, engineering approaches, intellectual property and regulatory strategies, and unique business model position us to develop and commercialize competitively differentiated products in our target areas of complex generics, follow-on biologics and novel therapeutics.

Our Technology

Our goal is to understand multi-dimensional complex mixtures and biological networks in order to create well-controlled manufacturing processes for products and unique approaches to targeting system biologies. We believe this provides us a competitive advantage in developing complex generics, follow-on biologics and novel therapeutics.

The first step in our approach is to gain a detailed understanding of the complex system we are studying. To do this, we deconstruct complex mixtures and biological networks and define the key attributes that can uniquely and unambiguously characterize relevant properties about the system. Key elements include use of existing and proprietary analytical technologies to measure the key attributes to

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ensure thorough and sufficient characterization, use of reagents, enzymes, labeling agents, and other tools to specifically and precisely understand and modify structural attributes of complex product candidates, and use of bioinformatics approaches that support the choice of analytics and enable predictive modeling of complex systems to assist in the characterization process.

The second step in our approach is to use the characterization information we have generated to engineer a well-controlled manufacturing process to ensure we can reliably produce complex mixture products. Key elements include mapping the elements of the system in which these products function to the manufacturing process this includes defining the structure-process relationships and development of process controls derived from our characterization analytics.

The third step in our approach is to apply our tools to biological systems. Most *in-vitro* and *in-vivo* biological assays are a result of a complex set of molecular interactions, and in using our tools we believe we can develop unique approaches to target biological systems. Key elements include use of advanced existing and proprietary analytics to develop a thorough understanding of targeted biological systems and thereby develop our product candidates.

It is the combination of these tools that enables us to thoroughly characterize complex polysaccharide, polypeptide and protein products. While a similar integrated analytical approach is applied across these different product categories, we develop a unique characterization toolkit for each specific complex molecule.

Commercial, Development and Research Programs

Our complex generic programs target marketed products that were originally approved by the U.S. Food and Drug Administration, or FDA, as New Drug Applications, or NDAs. Therefore, we were able to access the existing generic regulatory pathway and submit Abbreviated New Drug Applications, or ANDAs, for these products. Our first commercial product, enoxaparin sodium injection, which we developed and commercialized in collaboration with Sandoz, an affiliate of Novartis AG, received FDA marketing approval in July 2010 as a generic version of Lovenox. 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 ANDA submitted by our collaborative partner 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 such as Lovenox. From

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July 2010 through early October 2011, the enoxaparin marketed by Sandoz was the sole generic version of Lovenox, and consequently, under the terms of our collaborative agreement with Sandoz, we earned a substantial profit share on Sandoz' net sales of enoxaparin. In developing our enoxaparin product, we filed for patent protection for certain of our enoxaparin-related technology and we have sought, and continue to seek, to enforce our issued patents.

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. In our development of M356 we filed for patent protection for certain of our M356-related technology, and if necessary, we may seek to enforce issued patents relating to our M356 product.

Our follow-on biologics (FOBs) program is targeted toward developing biosimilar and interchangeable versions of marketed biologic therapeutics. 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 opens the market for biosimilar and interchangeable versions of a broad array of biologic therapeutics, including antibodies, cytokines, fusion proteins, hormones and blood factors. Forecasters predict a rapidly growing multi-billion dollar global market for these products. Most of these biologic therapeutics are complex mixtures, and for several years we have been investing in novel approaches to the structural characterization, process engineering and analysis of biologic systems. In February 2012, FDA released three documents containing their preliminary guidelines for applications under the Section 351(k) pathway. These guidelines confirmed that FDA will use a totality-of-the-evidence approach that puts a substantial emphasis on extensive structural and functional characterization in evaluating biosimilar products for approval. We believe the FDA guidances provide a framework for our follow-on biologics strategy. Our goal is to engineer biologic therapeutics that will show minimal structural or functional differences from the reference brand product, thereby justifying a more selective and targeted approach to non-clinical and/or human clinical testing to support demonstration of biosimilarity and interchangeability. In December 2011, we entered into a global collaboration with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, which we refer to collectively as Baxter, to develop and commercialize up to six follow-on biologics. Baxter is an established healthcare company with global product development, manufacturing and commercial capabilities.

Our novel therapeutics program leverages the capabilities and expertise built during the development of our complex generics and FOB programs to address unmet clinical needs. Our most advanced efforts have been in the area of polysaccharide mixtures. M402, our novel polysaccharide-based drug candidate, is in development as a potential anti-cancer agent that targets over five different key biological mechanisms involved in cancer progression and metastasis. Our other polysaccharide-based drug candidate, adomiparin, has been engineered to possess what we believe will be an improved therapeutic profile compared with other currently marketed anticoagulants to support the treatment of ACS. We will not move forward with further clinical trials of adomiparin unless we have a partner for that program. In addition to these two development candidates, we are also seeking to discover and develop additional novel drugs based either on the polysaccharide-based platform or on a biologics, or proteins and monoclonal antibody, platform. We have built significant capabilities in biological characterization and engineering of proteins through our FOB platform that allow us to create unique and novel formulations of protein and antibody drug compositions for specific disease indications. To add to these capabilities, in December 2011, we acquired selected assets of Virdante

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Pharmaceuticals, Inc. relating to "sialic switch" technology. Sialic acid is a type of sugar modification on selected proteins that is understood to regulate specific biological functions of these proteins. These assets add to our core ability to modify and engineer protein backbones to precisely regulate biological networks and develop novel biologic product candidates.

Product Programs Complex Generic and Follow-On Biologics

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 DVT and to support the treatment of 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. The current description in the package insert of Lovenox includes molecular weight distribution and *in vitro* measurements of Lovenox's ability to inhibit blood clotting factors Xa and IIa, or its anti-Xa and anti-IIa activity. While molecular weight distribution provides a rough measure of the range of chain lengths, it provides no information about detailed sequences or chemical structures contained in Lovenox. Similarly, the *in vitro* measures of anti-Xa and anti-IIa activity describe certain aspects of anticoagulation but only partly define the biological and clinical activity of Lovenox. According to Sanofi-Aventis, only 15% to 25% of the chains in LMWHs contain sequences that bind to the factor that is responsible for anti-Xa and anti-IIa activity. Our technology and analytical approach allowed us to thoroughly characterize Lovenox and enabled FDA approval of the ANDA.

In 2003, we entered into a collaboration with Sandoz N.V. and Sandoz Inc., affiliates of Novartis AG, which we refer to as the 2003 Sandoz Collaboration. Sandoz N.V. later assigned its rights and obligations under the 2003 Sandoz Collaboration to Sandoz AG, and we refer to Sandoz AG and Sandoz Inc. together as Sandoz. Under the 2003 Sandoz Collaboration, we and Sandoz agreed to exclusively develop, manufacture and commercialize enoxaparin sodium injection in the United States.

In July 2006, we entered into a Stock Purchase Agreement and an Investor Rights Agreement with Novartis Pharma AG, and in June 2007, we and Sandoz AG executed a definitive collaboration and license agreement, or the Definitive Agreement, pursuant to which we expanded the geographic markets covered by the 2003 Sandoz Collaboration related to enoxaparin sodium injection to include the European Union and further agreed to exclusively collaborate with Sandoz AG on the development and commercialization of other products for sale in specified regions of the world. We refer to this series of agreements collectively as the 2006 Sandoz Collaboration.

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 and the ANDA for the vial form of enoxaparin sodium injection was approved in December 2011.

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Commercial Market

In 2011, the U.S. enoxaparin market reached an estimated total of $2 billion in sales. Sanofi reported $883 million (€633million) in sales of Lovenox in the United States in 2011. Sandoz reported $1.0 billion in sales of enoxaparin sodium injection in the United States in 2011. Pursuant to the 2003 Sandoz Collaboration, Sandoz is responsible for commercialization and distribution of enoxaparin sodium injection.

Legal Matters

In July 2010, Sanofi-Aventis filed a lawsuit in the United States District Court for the District of Columbia against the FDA, Margaret A. Hamburg, Commissioner of Food and Drugs, and Kathleen Sebelius, Secretary of Health and Human Services. The complaint alleged, among other things, that the FDA's approval of the ANDA filed by Sandoz for enoxaparin sodium injection was arbitrary and capricious and exceeded FDA's statutory authority by requiring additional data for the purpose of demonstrating the safety or effectiveness of a generic version of Lovenox and departing from its own precedent governing the approval of generic drugs that have not been fully characterized. The lawsuit sought, among other things, a temporary restraining order and preliminary injunction directing the FDA to suspend and withdraw its approval of the ANDA filed by Sandoz for enoxaparin sodium injection. In August 2010, the court denied the motion for a temporary restraining order and preliminary injunction. In December 2010, Sanofi-Aventis filed a motion for summary judgment seeking a reversal of the FDA approval. The defendants filed responses opposing the motion and cross-motions seeking to affirm the approval of Sandoz's ANDA. In February 2012, the court denied Sanofi's motion for summary judgment and granted the defendants' cross-motions for summary judgment.

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. The patents claim methods of producing enoxaparin having specified quality attributes. We will continue to prosecute this case and enforce our patents.

In September 2011, we and Sandoz sued Amphastar Pharmaceuticals, Inc., or Amphastar, Watson Pharmaceuticals, Inc., or Watson, 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 Watson, Amphastar and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the court granted our motion for a preliminary injunction and entered an order enjoining Watson, Amphastar 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 requiring us and Sandoz to post a security bond of $100 million in connection with the litigation. Watson, Amphastar and International Medical Systems, Ltd. appealed the decision to the Court of Appeals for the Federal Circuit, and in January 2012, the Court of Appeals stayed the preliminary injunction, pending a decision on appeal. We will continue to pursue our claims in the District Court and we have confidence in the strength of our patents.

M356 Generic Copaxone

M356 is designed to be a generic version of Copaxone, also known as glatiramer acetate, a complex drug consisting of a mixture of polypeptide chains. Copaxone is indicated for reduction of the frequency of relapses in patients with RRMS, a chronic disease of the central nervous system characterized by inflammation and neurodegeneration.

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Description of Our Program

Under our 2006 Sandoz Collaboration, we and Sandoz AG agreed to jointly develop, manufacture and commercialize M356. 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.

Regulatory Matters

In December 2007, our collaborative partner, Sandoz, submitted to the FDA an ANDA in its name seeking approval to market 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 or 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. In addition, the FDA's published database indicates that the first substantially complete ANDA submitted for glatiramer acetate injection containing a Paragraph IV certification was filed on December 27, 2007, making Sandoz's ANDA eligible for the grant of a 180-day generic exclusivity period upon approval. Under applicable laws, there are a number of ways an ANDA applicant may forfeit its 180-day exclusivity, including if the applicant fails to achieve at least tentative approval within 30 months after the date on which the ANDA is filed. Because tentative approval for the M356 ANDA was not received in the specified 30 months, the 180-day exclusivity period will be forfeited unless the exception to the forfeiture rule applies. We will not know whether the exception applies unless and until the FDA approves the ANDA.

The review of Sandoz's ANDA is ongoing. We and Sandoz are in regular communication with the FDA to address any additional questions or requests that it may have as it continues the review of Sandoz's application.

Potential Commercial Market

In North America, Copaxone is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva. In Europe, Copaxone is marketed by Teva and Sanofi-Aventis. Teva reported worldwide sales of Copaxone of approximately $3.6 billion in 2011, with approximately 79%, or $2.8 billion, from the United States.

Legal Matters

Subsequent to FDA's acceptance of the ANDA for review, in August 2008, Teva and related entities sued Sandoz, Novartis AG and us in the United States District Court for the Southern District of New York for patent infringement related to four of the seven Orange Book patents listed for Copaxone. The court subsequently dismissed all claims in the case against Sandoz International GmbH and Novartis AG, the foreign affiliates of Sandoz. We and Sandoz asserted defenses of non-infringement, invalidity and unenforceability 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 was held in two phases: in July 2011 on the issue relating to inequitable conduct and in September 2011 for the remaining issues in the consolidated case. Post-trial briefs have been filed and a decision is pending.

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In a separate lawsuit, in December 2009, Teva and related entities sued Sandoz, Novartis AG and us for patent infringement related to certain non-Orange Book patents titled "Copolymer 1 related polypeptides for use as molecular weight markers and for therapeutic use". We and Sandoz filed a motion to dismiss, and a motion to stay litigation pending resolution of the motion to dismiss. Both motions were opposed by Teva and are pending. The court subsequently dismissed all claims in the case against Sandoz International GmbH and Novartis AG, the foreign affiliates of Sandoz. There is no defined timeline for the court to rule in either suit.

Follow-On Biologics (FOBs) Program

Description of Our Program

We are also applying our technology platform to the development of FOBs, including both interchangeable biologics (or biosimilars designated by FDA to be interchangeable) and biosimilar versions of marketed therapeutic proteins. Therapeutic proteins represent a sizable segment of the U.S. drug industry, with sales expected to be approximately $60 billion in 2012. Given the inadequacies of standard technology, 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 that our investment in our analytics and characterization technology coupled with our investment in the science of better understanding the relationship of the biologic manufacturing process to structural composition provides us with the opportunity develop a competitive advantage for our future FOB product candidates.

In December 2011, we and Baxter entered into a Development, License and Option Agreement, or the Baxter Agreement, under which we agreed to collaborate, on a world-wide basis, on the development and commercialization of up to six follow-on biologic products. The Baxter Agreement became effective in February 2012.

Regulatory Matters

Most protein drugs have been approved by the FDA under the Biologics License Application, or 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 generic 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 FOBs was created. The new abbreviated regulatory pathway establishes 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.

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In December 2011, the FDA released 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 development, non-clinical and clinical requirements for a biosimilar or interchangeable biologic product.

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.

Product Candidates Novel Drugs

Overview

Our novel drug research and development program uses the established characterization and process engineering capabilities from our complex generic and FOB programs with a focus on cell surface polysaccharides and therapeutic proteins.

M402

M402 is a novel polysaccharide-based product candidate and is engineered to have potent anti-cancer properties and low anticoagulant activity. Polysaccharide-based compounds like heparin are complex molecules present in the tumor microenvironment which present growth factors, cytokines, and chemokines necessary for tumor cell growth, migration and survival. M402 is designed to exploit this biology by binding to and down regulating multiple factors involved in disease progression and metastasis. Data from multiple preclinical studies have shown that M402 has the potential to modulate angiogenesis and tumor progression and metastasis through a variety of polysaccharide-based-binding proteins.

A preclinical study, in collaboration with the Cancer Research Institute (Cambridge, UK), demonstrated the efficacy of M402 in a murine pancreatic cancer model. The study showed that M402, in combination with gemcitabine, significantly improved survival and substantially lowered the incidence of metastasis compared to mice treated with gemcitabine alone.

We currently have plans to advance M402 into human clinical trials in 2012. It is anticipated that M402 will be used in combination with standard-of-care cytotoxic regimens for the treatment of advanced malignancies.

Adomiparin

Our other novel drug candidate, adomiparin, has been engineered to possess what we believe will be an improved therapeutic profile compared with other currently marketed anticoagulants to support the treatment of ACS. We will not move forward with further clinical trials of adomiparin unless we have a partner for the program.

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Discovery Program

We believe our core analytical tools enable new insights into exploring the biology of many diseases, which will lead to an enhanced understanding of the relative role of different biological targets and related cell-to-cell signaling pathways. Many complex diseases are a result of multiple biological phenomenon that have been offset. Our goal is to leverage the multi-targeting nature of complex mixture molecules to develop novel therapeutics which we could positively affect multiple pathways in a disease. Our core technology platform enables us to map the critical nodes that regulate complex diseases and then use the appropriate collection of "drugs" whether polysaccharides, proteins, peptides or monoclonal antibodies to target the appropriate nodes simultaneously. This unique approach, while early, opens up the range of diseases that can be targeted.

Research and Development Expenses

Research and development expenses consist of costs incurred in identifying, developing and testing our product programs. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, contract research and manufacturing, and the costs of laboratory equipment and facilities. Research and development expense for 2011 was $64.7 million, compared with $51.7 million in 2010 and $60.6 million in 2009.

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 injectable enoxaparin 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 is one or more third-party competitors 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 us 45% of the contractual profits from the sale of enoxaparin sodium injection. 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 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, and then a profit share, which occurred late in the fourth quarter of 2011. Additionally, in October 2011, FDA approved the ANDA for the enoxaparin product of Amphastar and Watson. 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 U.S. District Court, Watson announced that they and Amphastar intended to launch their enoxaparin product. Sandoz confirmed to us that the Amphastar/Watson product has been marketed as of the end of January 2012. Consequently, in each product year, Sandoz is obligated to pay us a royalty on net sales, 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%.

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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 in each of the next four years, but we do not expect the amount of any future payment due to the annual adjustment to be material.

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. In addition, if Sandoz terminates the agreement due to our uncured breach, Sandoz would retain its rights of first refusal outside the United States.

2006 Sandoz Collaboration

Under the 2006 Sandoz Collaboration, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356 and two other follow-on products for sale in specified regions of the world 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

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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 2006 Sandoz Collaboration now principally governs the M356 collaborative program and the expansion of the enoxaparin sodium injection 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 2006 Collaboration; 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 profits from sales of M356. We are eligible to receive up to $163.0 million in milestone payments if all milestones are achieved for the two product programs remaining under collaboration. 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 2006 Sandoz Collaboration, 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 Definitive 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 Definitive Agreement. The Definitive Agreement may be terminated if either party breaches the Definitive Agreement or files for bankruptcy. In addition, either we or Sandoz AG may terminate the Definitive 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 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.

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Baxter

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 two follow-on biologic products. In addition, Baxter has the right to select up to four additional follow-on biologic products to be included in the collaboration. The Baxter Agreement became effective on February 13, 2012, following expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended.

Under the terms of the Baxter Agreement, Baxter agreed to pay us:

- an upfront payment of $33 million;
- technical and development milestone payments totaling up to $91 million across the six product candidates;
- regulatory milestones totaling up to $300 million, on a sliding scale, across the six 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;
- option payments totaling $28 million for the exercise of the options with respect to the additional four product candidates, and payments of $5 million each for extensions of the period during which such additional products may be named; and
- 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.

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 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, we will generally be responsible for research and process development costs prior to the effective date of an Investigational New Drug, or IND, exempton, or its equivalent or waiver or regulatory authority authorization to dose humans, subject to certain restrictions as outlined in the Baxter Agreement. The cost of in-human clinical trials, manufacturing in accordance with current good manufacturing practices, or cGMP, and commercialization will be borne by Baxter.

Under the Baxter Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all therapeutic indications. In addition, we have agreed, for a period commencing six months following the effective date and ending on the earlier of three years from the effective date of the Baxter Agreement (subject to certain limited time extensions, as provided in the Baxter Agreement) or the selection of the four additional products, to notify Baxter of bona fide offers from third parties to develop or commercialize a follow-on biologic product 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 in

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the Baxter Agreement), we may develop, on our own or with a third party, any FOB products not named under the Baxter Agreement, subject to certain restrictions as more fully described in the Baxter Agreement.

The collaboration is governed by 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.

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;
- 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; or
- 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.

Massachusetts Institute of Technology

We have two patent license agreements with the Massachusetts Institute of Technology, or M.I.T., granting us various exclusive and nonexclusive 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
- synthesis methods.

We must meet certain diligence requirements in order to maintain our licenses under the two agreements. Under the agreements, we must expend at least $1.0 to $1.2 million per year towards the research, development and commercialization of products and processes covered by the agreements. In addition, we are obligated to make first commercial sales and meet certain minimum sales thresholds of products or processes including, under the amended and restated agreement, a first commercial sale of a product or process no later than June 2013 and minimal sales of products thereafter ranging from $0.5 million to $5.0 million annually. M.I.T. may convert the exclusive licenses granted to us under the amended and restated license agreement to non-exclusive licenses, as its sole remedy, if we fail to meet our diligence obligations. Under the license agreement covering sequencing machines, M.I.T. has the right to treat a failure by us to fulfill our diligence obligations as a material breach of the license agreement.

In exchange for the licenses granted in the two agreements, we have paid M.I.T. license issue fees and we pay annual license and maintenance fees ranging, in the aggregate, from $132,500 to $157,500. We are also required to pay M.I.T. 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. We recorded $157,500, $157,500 and $132,500 as license and maintenance fees in the years ended December 31, 2011, 2010 and 2009, respectively, and $6.6 million and $2.0 million as royalty fees and

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milestone payments in the years ended December 31, 2011 and 2010, respectively, related to these agreements.

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.

Each 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 30 United States patents and foreign counterparts of some of those. We expect that additional patents will issue from presently pending U.S. and foreign patent applications. Any such patent will have a term of 20 years from the filing date of the underlying application. M.I.T. may terminate either 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 either agreement for any reason upon six months' notice to M.I.T., and, under one agreement, we can separately terminate the license under a certain subset of patent rights upon three months' notice.

We granted Sandoz a sublicense under the amended and restated license 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.

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 75 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 polysaccharides 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, including adomiparin and M402;
- methods to identify, analyze and characterize glycoproteins; and
- methods of manufacture of certain polysaccharide, polypeptide and glycoprotein products.

A significant portion of our patent portfolio covering methods and technologies for characterizing polysaccharides consists of patents and patent applications owned and licensed to us by M.I.T. In addition, a significant 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

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and enzymes in the characterization of sugars, and certain methods and technologies for analyzing polysaccharides 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 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 sialic switch assets of Virdante Pharmaceuticals, Inc., including intellectual property and cell lines, relating to the sialylation of intravenous immunoglobulin 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 anniversary 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

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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 the consolidated balance sheet as of December 31, 2011. 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.

The starting material for manufacture of M402 and enoxaparin sodium injection is unfractionated heparin, or UFH, including UFH from suppliers who source the materials from China. In 2008, due to the occurrence of adverse events associated with the use of contaminated UFH, there were global recalls, including in the United States, of UFH products. Based on its investigation, 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. As a result of these UFH product recalls and potential future recalls, the United States government has placed certain restrictions, and may decide to place additional restrictions, on the import of raw materials,

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including UFH. In addition, these restrictions have limited the number of suppliers who are able to provide UFH. Both of these factors could make it difficult for us to obtain our starting material, could increase costs significantly or make these materials unavailable.

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, an FOB may also be able to file 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.

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Generic drug applications are termed "abbreviated" because they are not required to duplicate the clinical (human) testing or, generally, preclinical 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

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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 company'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

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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.

Follow-On Biologics

With the enactment of federal healthcare reform legislation in March 2010, the BPCI was enacted which created a new abbreviated approval pathway for FOBs. 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 FOBs. 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.

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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;

- animal 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 December 2011, the FDA released its proposed 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, non-clinical 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.

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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 preclinical laboratory tests, animal 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 non-clinical and or clinical testing sites; and
- FDA review and approval of the NDA or BLA.

Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical 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

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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 preclinical 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 FOBs. Under the law, the FDA must wait four years after approval of a biologic

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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

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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 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. Many of our competitors already market or are working to develop products similar to those we are developing and have considerable experience in product development and in obtaining regulatory approval to market pharmaceutical products. In addition, the development and commercialization of complex generic products and FOBs is inherently competitive as a result of existing brand competition at the time of product launch. Certain of these 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-Aventis, the company currently marketing Lovenox, and faces competition from other companies. In October 2011, through its authorized third-party distributor, Sanofi-Aventis marketed its generic product. In December 2011, Sanofi-Aventis announced its intention to withdraw its competing authorized generic. In January 2012, Watson and Amphastar launched their enoxaparin product. As a result, Sandoz may have to lower its prices for our enoxaparin sodium injection product and we may also lose market share. In addition, Sanofi-Aventis may choose to re-market a generic version of Lovenox itself or through an authorized third-party distributor. In addition, ANDAs have been submitted to the FDA by Teva, Hospira, Inc., and other ANDAs or other regulatory applications may have been submitted or may be submitted in the future.

In addition, other anticoagulants used in the treatment of DVT and ACS will compete with enoxaparin sodium injection. These competitive products include GlaxoSmithKline plc's Factor Xa

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inhibitor, Arixtra®, which is approved in the prevention and treatment of several DVT indications, and other LMWH products. We are also aware of other injectable and oral anticoagulant drugs in development for the treatment of DVT, including next-generation LMWHs and several oral Factor Xa or Factor IIa inhibitors that are in clinical trials. The Factor Xa inhibitors include apixaban, which is being developed by Bristol-Myers Squibb Company and rivaroxaban (Xarelto®), which is approved in the U.S. for DVT prophylaxis and the reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation. Xarleto® is marketed worldwide by Bayer AG and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. The Factor IIa inhibitors in development include 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 being further developed by Boehringer Ingelheim GmbH for DVT prophylaxis.

In the event that we receive approval for, market and sell M356, a generic version of Copaxone, we would face competition from a number of sources, including branded Copaxone, which is marketed by Teva Neuroscience, Inc. in the United States and is co-promoted by Teva Pharmaceutical Industries Ltd. and Sanofi-Aventis in Europe. 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 & Synthon Pharmaceuticals, Inc., and 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 U.S. 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.; Betaseron (interferon-beta-1b), which is marketed by Bayer HealthCare Pharmaceuticals Inc., the U.S. 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; and Novantrone (mitoxantrone for injection concentrate) marketed by EMD Serono, Inc.

In addition to the marketed products, a number of companies are working to develop products to treat multiple sclerosis. For example, BG-12, developed by Biogen Idec Inc., an oral compound that is being tested in relapsing multiple sclerosis. Also, Genzyme Corporation is testing Lemtrada (alemtuzumab), a once annual infusion compound, for the treatment of relapsing multiple sclerosis.

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 FOBs. Amgen Inc. has announced a collaboration with Watson Pharmaceuticals, Inc., Biogen Inc. has announced a collaboration with Samsung and companies such as Sandoz, Pfizer Inc., Hospira, Merck and Teva have announced intentions to enter the FOB business. Many of these companies are significantly larger than us, have substantially greater financial resources and have significant pre-existing resources to devote to the FOB resources. 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 therapeutics.

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

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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. 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., Keryx Pharmaceuticals, Endotis 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, 2011, we had 197 employees, including a total of 61 employees who hold M.D. or 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 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 subsidiaries.

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.

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Item 1A. RISK FACTORS

Investing in our stock involves a high degree of risk. You should carefully consider the risks and uncertainties 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 continue to generate significant revenue, we may not be profitable.

We have incurred significant losses since our inception in May 2001. At December 31, 2011, our accumulated deficit was $103.4 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 profitability will also be dependent on the entry of competitive products and, if so, 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. We may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to remain profitable would cause the market price of our common stock to decrease and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

Our revenue is dependent on the continued successful manufacture and commercialization of enoxaparin sodium injection, and marketing of another generic Lovenox product may adversely affect our revenue.

Our near-term ability to generate revenue, in large part, depends on the continued successful commercialization of enoxaparin sodium injection. This further depends, in large part, on Sandoz's continued success in manufacturing and commercializing the product, maintaining market share and competing with Lovenox brand competition as well as other generic competition.

Although our revenue for the first four quarters of enoxaparin sodium injection sales was significant, Sandoz was paying us 45% of the contractual profits from the sale of enoxaparin sodium injection during that period. In October 2011, Sandoz confirmed that an authorized generic version of Lovenox had launched, and, as a result, under the 2003 Sandoz Collaboration, Sandoz instead paid us a royalty on its net sales of enoxaparin sodium for a significant portion of the fourth quarter of 2011 before reverting to a profit share late in the fourth quarter of 2011. In January 2012, Watson and Amphastar launched their enoxaparin product. As a result, under the 2003 Sandoz Collaboration, rather than paying us a profit share of 45% of contractual profits, Sandoz is now obligated to pay us a royalty on net sales. In each product year, which begins July 1, for net sales up to a pre-defined sales threshold the royalty is payable at a 10% rate, and for net sales above the sales threshold the royalty rate increases to 12%.

In addition, Teva and Hospira have each submitted ANDAs for generic versions of Lovenox with the FDA, and other third parties may seek approval to market generic versions of Lovenox in the

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United States. Additional generic competition would ordinarily lead to a loss of market share as well as a significant decline in pricing.

The change in Sandoz contractual payment obligations, along with additional generic competition, will cause our revenue from enoxaparin sodium injection to be significantly reduced compared to the period from July 2010 through December 2011 and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer. We cannot predict the extent to which the additional competition, and any resulting price reductions, will have on the amount of Sandoz' net sales and, consequently, on our future revenue levels.

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.

In September 2011, following approval of the ANDA filed by Amphastar for enoxaparin, we sued Amphastar, Watson and International Medical Systems, Ltd. in the United States District Court for the District of Massachusetts for infringement of two of our patents that cover innovative methods of producing enoxaparin sodium which assure that the commercial product meets standards for identity and quality. Although the court granted our motion for preliminary injunction enjoining Amphastar, Watson and International Medical Systems, Ltd. from marketing a generic Lovenox product, the court required us and Sandoz to post a security bond of $100 million and Amphastar, Watson and International Medical Systems, Ltd. filed a notice to appeal the decision and an emergency motion to dissolve or stay the preliminary injunction. In January 2012, the court of appeals stayed the preliminary injunction. In January 2012, Watson and/or Amphastar began marketing their generic Lovenox. Under these circumstances, the resulting market price for our enoxaparin sodium injection product may be lower, we may lose significant market share for enoxaparin sodium injection, and significantly less favorable economic terms for us under the 2003 Sandoz Collaboration have been triggered. While the patent litigation is continuing in the district court, if we are not successful in the patent case and do not succeed in obtaining injunctive relief, or damages for our lost profits due to infringing sales, our revenue would be irrevocably significantly reduced and our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer. Furthermore, in the event that we lose the case in the District Court, it is determined that the preliminary injunction was improvidently granted, and Amphastar and Watson are able to prove they suffered damages as a result of the injunction during the period the preliminary injunction was in effect, then we could be liable for such damages for up to $35 million of the security bond.

In December 2010, we sued Teva in the United States District Court for the District of Massachusetts for infringement of our two patents that cover the innovative methods of producing enoxaparin sodium. If we are not successful in this patent case and do not succeed in obtaining injunctive relief, or 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 be lower 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 Sanofi-Aventis or others to limit or prevent the use of our enoxaparin sodium injection product are successful, our business may suffer.

In February 2003, Sanofi-Aventis filed a Citizen Petition with the FDA requesting that the FDA withhold approval of any ANDA for a generic version of Lovenox. In July 2010, the FDA denied Sanofi-Aventis' Citizen Petition and approved the ANDA filed by Sandoz for enoxaparin sodium injection. Sanofi-Aventis then filed a lawsuit in the United States District Court for the District of

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Columbia against the FDA, Margaret A. Hamburg, Commissioner of Food and Drugs, and Kathleen Sebelius, Secretary of Health and Human Services. The complaint alleged, among other things, that FDA's approval of the ANDA filed by Sandoz was arbitrary and capricious and exceeded FDA's statutory authority by requiring additional data for the purpose of demonstrating the safety or effectiveness of a generic version of Lovenox and departing from its own precedent governing the approval of generic drugs that have not been fully characterized. In December 2010, Sanofi-Aventis filed a motion for summary judgment seeking a reversal of the FDA approval and the defendants each filed responses opposing the motion and cross-motions seeking to affirm the approval of Sandoz's ANDA for enoxaparin sodium injection. In February 2012, the court denied Sanofi's motion for summary judgment and granted the defendants' cross-motions for summary judgment. Sanofi may decide to appeal that decision.

If Sanofi-Aventis appeals the decision and is successful in its appeal, approval of the ANDA may be reversed. A reversal may block continued sales of enoxaparin sodium injection, which would materially harm our business.

If efforts by manufacturers of branded products to delay or limit the use of generics or FOBs are successful, our sales of generic and FOB products may suffer.

Many manufacturers of branded products have increasingly used legislative, regulatory and other means to delay competition from manufacturers of generic drugs and could be expected to use similar tactics to delay competition from FOBs. These efforts have included:

- settling patent lawsuits with generic companies, resulting in such patents remaining an obstacle for generic 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 applications;
- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of generic drug applications;
- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug 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; and
- attaching 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, all of which 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 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.

Further, some manufacturers of branded products have engaged in state-by-state initiatives to enact legislation that restricts the substitution of some branded drugs with generic drugs. If these

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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.

Our patent litigation with Teva, the manufacturer of Copaxone, may cause delays and additional expense in the commercialization of M356. If we are not successful in commercializing M356 or are significantly delayed in doing so, our business may be materially harmed.

In August 2008, Teva and related entities sued Sandoz, Novartis AG and us for patent infringement in the United States District Court for the Southern District of New York related to four of the seven Orange Book patents listed for Copaxone. We and Sandoz Inc. asserted defenses of non-infringement, invalidity and unenforceability 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, 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. In April 2011, Teva filed a motion for summary judgment of no inequitable conduct. In June, 2011, the court denied Teva's motion and granted a bench trial, which occurred in July 2011, to hear the issue of inequitable conduct only. The trial on the remaining issues occurred in September 2011 in the consolidated case. Post-trial briefs have been filed and a decision is pending. There is no defined timeframe for the court to issue a decision.

In a separate lawsuit, in December 2009, Teva and related entities sued Sandoz, Novartis AG and us for patent infringement related to certain non-Orange Book patents. We and Sandoz filed a motion to dismiss this case, and a motion to stay litigation pending resolution of the motion to dismiss. Both motions were opposed by Teva and are pending.

These lawsuits could significantly delay, impair or prevent our ability to commercialize M356, our second major generic product candidate. Litigation involves many risks and uncertainties, and there is no assurance that Sandoz or we will prevail in any lawsuit with Teva. In addition, Teva has significant resources and any litigation with Teva could last a number of years, potentially delaying or prohibiting the commercialization of M356. If we are not successful in commercializing M356 or are significantly delayed in doing so, our business may be materially harmed.

If other generic versions of our product candidates, including M356, are approved and successfully commercialized, our business would suffer.

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. 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 penetration. As this happens, or 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 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.

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If the market for a reference brand product, including Lovenox or Copaxone, significantly declines, sales or potential sales of our generic product and generic or biosimilar 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, including Lovenox or Copaxone, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product obsolete. 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.

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, including enoxaparin sodium injection. 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

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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.

We will require substantial additional funds 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, 2011, we had cash, cash equivalents and marketable securities totaling $348.4 million and accounts receivable of $28.2 million. For the year ended December 31, 2011, we had a net income of $180.4 million and cash provided by operating activities of $213.7 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, preclinical 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 rate of sales of enoxaparin sodium injection;
- a decision is issued in favor of Teva in its patent litigation matters against us;
- the advancement of our product candidates and other development programs, including the timing and costs of obtaining regulatory approvals;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation, including with Amphastar and Watson 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 preclinical 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 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 2014. We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and debt financings. 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.

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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 preclinical 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 product candidates, the differential availability of clinical data and experience between a brand manufacturer that conducts clinical trials and a generic manufacturer;
- 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
- for our innovative products, 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.

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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 prevent us from being profitable.

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;
- the success and extent of our physician education and marketing programs;
- the clinical, medical affairs, sales, distribution and marketing efforts of competitors; and
- the availability and amount of government and third-party payor reimbursement.

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

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

We are dependent on the members of our management team for our business success. Our employment arrangements with our executive officers are terminable by either party on short notice or no notice. We do not carry life insurance on the lives of any of our personnel. The loss of any of our

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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.

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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

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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 preclinical or clinical test results, to determine therapeutic equivalence or to confirm that any inactive ingredients or impurities do not compromise the product's safety and efficacy. Provision of sufficient information for approval may be difficult, expensive and lengthy. We cannot predict whether M356 will receive FDA approval as therapeutically equivalent to Copaxone.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of Copaxone, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of M356 could be delayed or prevented or become more expensive. Delays in any part of the process or our inability to obtain regulatory approval for M356 could adversely affect our operating results by restricting or significantly delaying our introduction of M356.

Even if we are able to obtain regulatory approval for our generic product candidates as therapeutically equivalent, 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 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. As a result, in states that do not deem our product candidates therapeutically equivalent, physicians will be required to specifically prescribe a generic product alternative rather than have a routine substitution at the pharmacy level for the prescribed 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.

Although health care reform legislation that establishes a regulatory pathway for the approval by the FDA of follow-on biologics has recently been enacted, the standards for determining sameness or similarity for follow-on biologics are only just being implemented by the FDA. Therefore, substantial uncertainty remains about the potential value our proprietary technology platform can offer to FOB 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 follow-on biologics. 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 products, which in addition to being biosimilar can produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. Only interchangeable biosimilar

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products would be considered interchangeable at the retail pharmacy level. 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, non-clinical 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 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:

- an obligation of the applicant to share, in confidence, the information in its abbreviated pathway application with the brand company's and patent owner's counsel as a condition to using the new patent clearance process;
- 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 modified product that qualifies for an additional 12-year marketing exclusivity period, reducing the opportunity for substitution at the retail pharmacy level for an interchangeable FOB. Finally, the new legislation also creates the risk that, as brand and FOB 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 FOB approval.

Several states have challenged the healthcare reform legislation as unconstitutional, and at least two federal courts have ruled that it is unconstitutional in whole or in part. These cases have been appealed and the ultimate outcome may not be known for several years. 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 declared unconstitutional, is significantly amended or is repealed, our opportunity to develop biosimilar (including interchangeable) biologics could be lost and our business could be materially and adversely affected.

If our preclinical 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 drug candidates, we are required to demonstrate through preclinical studies and clinical trials that our drug development candidates are safe and effective. Preclinical 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 preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical studies

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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 preclinical studies or clinical trials may produce negative or inconclusive results, and we may be required to conduct additional preclinical 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; and
- 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.

The results from preclinical 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.

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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, we will be subject to comprehensive compliance obligations under state and federal reimbursement, 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;

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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.

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

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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 that could significantly change the U.S. 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 follow-on biologics 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 FOBs and adjusting reimbursement for FOBs, the new law could promote the development and commercialization of FOBs. However, given the uncertainty of how the law will be interpreted and implemented, the impact of the law on our strategy for follow-on 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 FOB 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 follow-on biologics based on cost savings, it could also have the effect of reducing follow-on biologic market share.

The financial impact of this U.S. 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 U.S. 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 U.S. 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

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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. For the years ended December 31, 2011, 2010 and 2009, we spent approximately $52,000, $57,000 and $125,000, respectively, in order to comply with environmental and waste disposal regulations. 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. The FDA has proposed legislation that would enact user fees to fund additional resources and that would be accompanied by statutory review periods to the address this backlog and the delays. Currently, the FDA is obligated to give priority to NDA and BLA applications that are subject to statutory review time periods. Until such time as resources are increased by 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.

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Assuming the other requirements for patentability are met, currently, in the United States, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States will transition to a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application will be 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 parties* 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.

Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims allowed in any patents issued to us or to others.

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.

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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 allegedly or been 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 become 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 resort to litigation to enforce a patent issued to us or to determine the scope and validity of third-party patent or other proprietary rights 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.

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We in-license a significant 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, that give us rights to intellectual property that is necessary for 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

Our 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 collaboration and license agreement, or Definitive Agreement, we executed with Sandoz in June 2007, as amended, 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 Definitive 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

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Sandoz terminates the Definitive 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 Definitive 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 Definitive 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.

Our 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 FOB 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 FOB 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.

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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 preclinical 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

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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 of enoxaparin sodium injection to sustain commercial success or to meet expectations of securities analysts;
- failure to obtain FDA approval for the M356 ANDA;
- 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;
- 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;
- litigation involving our company or our general industry or both, including litigation pertaining to the launch of our, our collaborative partners' or our competitors' products;
- a decision in favor of or against Amphastar and Watson in the current patent litigation matters, or a settlement related to any case;

adverse FDA decisions regarding the development requirements for one or our FOB 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;

failure to demonstrate therapeutic equivalence, biosimilarity or interchangeability with respect to our technology-enabled generic product candidates or FOBs;

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demonstration of or failure to demonstrate the safety and efficacy for our novel development 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 strategic partnerships;

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.

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Item 2. PROPERTIES

As of February 1, 2012, pursuant to our sublease agreements, we lease a total of approximately 147,075 square feet of office and laboratory space in Cambridge, Massachusetts:

Property Location	Approximate Square Footage	Use	Lease Expiration Date
675 West Kendall Street Cambridge, Massachusetts 02142	78,500	Laboratory and Office	04/30/2015
*320 Bent Street Cambridge, Massachusetts 02141	68,575	Laboratory and Office	07/15/2013
	147,075		

*

Short-term sublease for overflow space.

Item 3. LEGAL PROCEEDINGS

In August 2008, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against us, Sandoz and Novartis AG in the United Stated 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 alleges infringement by us, Sandoz and Novartis AG of Orange Book patents owned by Yeda and licensed by Teva and seeks monetary, injunctive and declaratory relief. In November 2008, we and Sandoz each filed responsive pleadings denying the allegations of infringement, setting forth affirmative defenses based on invalidity, non-infringement and inequitable conduct and counterclaims seeking declaratory relief that the patent rights of Teva and Yeda pertaining to M356 are either not infringed, invalid or unenforceable. 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. In April 2011, Teva filed a motion for summary judgment of no inequitable conduct. In June 2011, the court denied Teva's motion and granted a bench trial, which occurred in July 2011, to hear the issue of inequitable conduct only. The trial on the remaining issues occurred in September 2011 in the consolidated case. Post-trial briefs have been filed and a decision is pending. There is no defined timeframe for the court to issue a decision.

In December 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and us for patent infringement related to certain non-Orange Book patents after Teva's motion to add those patents to the ongoing Paragraph IV litigation was denied. In January 2010, we and Sandoz filed a motion to dismiss this second suit on several grounds, including the failure of Teva to state an actionable legal claim and lack of subject matter jurisdiction. The motion is pending.

While we have vigorously defended these suits, a delay in a final judgment could significantly delay, impair or prevent our ability to commercialize M356 and our business could be materially harmed. Litigation involves many risks and uncertainties, and there is no assurance that Novartis AG, Sandoz or we will prevail in either lawsuit.

In September 2011, we sued Amphastar Pharmaceuticals Inc. ("Amphastar"), Watson Pharmaceuticals Inc. ("Watson"), 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, Watson and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the court granted our

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motion for a preliminary injunction and entered an order enjoining prevent Amphastar, Watson 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. Amphastar, Watson and International Medical Systems, Ltd. appealed the decision to the Court of Appeals for the Federal Circuit, and in January 2012 the Court of Appeals stayed the preliminary injunction pending a decision on appeal. In the event that we lose the case at the District Court, it is determined that the preliminary injunction was improvidently granted and Amphastar and Watson are able to prove they suffered damages as a result of the injunction during the period the preliminary injunction was in effect, we could be liable for such damages up to $35 million of the security bond.

While we intend to vigorously prosecute this action against Watson and Amphastar, and we believe that we can ultimately prove our case in court, this suit could last a number of years. As a result, absent preliminary injunctive relief, recovery of lost profits and damages could await a final judgment after an appeal of a district court decision. 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.

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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, 2010	$ 16.45	$ 12.10
June 30, 2010	15.30	10.77
September 30, 2010	26.20	11.23
December 31, 2010	17.66	13.53
March 31, 2011	17.40	12.32
June 30, 2011	20.70	15.24
September 30, 2011	21.00	10.15
December 31, 2011	18.20	10.77

Holders

On February 15, 2012, the approximate number of holders of record of our common stock was 40.

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.

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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, 2006 through December 31, 2011, 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 12/31/06 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

	12/31/06	12/31/07	12/31/08	12/31/09	12/31/10	12/31/11
Momenta Pharmaceuticals, Inc.	$ 100.00	$ 45.39	$ 73.74	$ 80.10	$ 95.17	$ 110.55
The NASDAQ Composite Index	$ 100.00	$ 110.26	$ 65.65	$ 95.19	$ 112.10	$ 110.81
The NASDAQ Biotechnology Index	$ 100.00	$ 102.53	$ 96.57	$ 110.05	$ 117.19	$ 125.54

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.

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Item 6. SELECTED CONSOLIDATED FINANCIAL DATA

The selected consolidated financial data set forth below with respect to our statement of operations data for the years ended December 31, 2011, 2010 and 2009 and the balance sheet data as of December 31, 2011 and 2010 are derived from our audited financial statements included in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2008 and 2007 and the balance sheet data as of December 31, 2009, 2008 and 2007 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 income (loss) per share. The selected consolidated financial data set forth below should be read in conjunction with and is qualified in its entirety by our audited consolidated financial statements and related notes thereto found 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

	Year Ended December 31,				
	2011	**2010**	**2009**	**2008**	**2007**
	(In thousands, except per share information)				
Statements of Operations Data:					
Collaboration revenue:					
Product revenue	$ 270,473	$ 96,625	$	$	$
Research and development revenue	12,595	20,147	20,249	14,570	21,561
Total collaboration revenue	283,068	116,772	20,249	14,570	21,561
Operating expenses:					
Research and development	64,657	51,712	60,612	55,301	69,899
General and administrative	38,710	28,595	23,800	24,591	28,219
Total operating expenses	103,367	80,307	84,412	79,892	98,118
Operating income (loss)	179,701	36,465	(64,163)	(65,322)	(76,557)
Interest income	746	176	825	3,483	8,484
Interest expense	(91)	(329)	(570)	(798)	(808)
Other income (expense)		978	(104)		
Net income (loss)	$ 180,356	$ 37,290	$ (64,012)	$ (62,637)	$ (68,881)
Net income (loss) per share:					
Basic	$ 3.62	$ 0.84	$ (1.60)	$ (1.74)	$ (1.93)
Diluted	$ 3.55	$ 0.81	$ (1.60)	$ (1.74)	$ (1.93)
Shares used in calculating earnings per share:					
Basic	49,852	44,626	40,056	35,960	35,639
Diluted	50,823	45,942	40,056	35,960	35,639

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	As of December 31,				
	2011	2010	2009	2008	2007
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 49,245	$ 100,681	$ 21,934	$ 55,070	$ 33,038
Marketable securities	299,193	52,078	73,716	53,461	102,899
Working capital	383,393	196,650	85,753	93,483	125,293
Total assets	420,909	227,569	118,451	132,201	168,298
Total long-term obligations	1,803	3,814	7,949	13,604	7,971
Total liabilities	17,831	21,466	24,289	32,696	40,758
Accumulated deficit	(103,403)	(283,759)	(321,049)	(257,037)	(194,400)
Total stockholders' equity	403,078	206,103	94,162	99,505	127,540

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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 includes 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

We are a biotechnology company specializing in the structural characterization, process engineering and biologic systems analysis of complex molecules, including polysaccharides, polypeptides, and proteins. Our initial technology was built on the ability to characterize complex polysaccharides. Over the last decade, we have expanded our expertise into technologies that enable us to develop a diversified product portfolio of complex generic, follow-on biologic, and novel therapeutics. Our business strategy has been to develop both generic and novel therapeutics, and we are working with collaborative partners to develop and commercialize our complex generics and follow-on biologics. This strategy was validated by the marketing approval and commercial launch of enoxaparin sodium injection, a generic version of Lovenox® in July 2010. Since its launch through December 31, 2011, we have recorded enoxaparin product revenues totaling $357 million, driven primarily by its initial status as a sole generic. We believe that our scientific capabilities, engineering approaches, intellectual property and regulatory strategies, and unique business model positions us to develop and commercialize competitively differentiated products in our target areas of complex generics, follow-on biologics and novel therapeutics.

Our complex generic programs target marketed products that were originally approved by the U.S. Food and Drug Administration, or FDA, as New Drug Applications, or NDAs. Therefore, we were able to access the existing generic regulatory pathway and submit Abbreviated New Drug Applications, or ANDAs, for these products. Our first commercial product, enoxaparin sodium injection, which we developed and commercialized in collaboration with Sandoz, an affiliate of Novartis AG, received FDA marketing approval in July 2010 as a generic version of Lovenox. 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 ANDA submitted by our collaborative partner 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 such as Lovenox. Following its approval of the enoxaparin ANDA, FDA issued a document that detailed the five scientific criteria it applied to determine that the ANDA met the statutory requirements for approval of an interchangeable generic drug. From July 2010 through early October 2011, the enoxaparin marketed by Sandoz was the sole generic version of Lovenox, and consequently, under the terms of our collaborative agreement with Sandoz, we earned a substantial profit share on Sandoz' net sales of enoxaparin. In developing our enoxaparin product, we filed for patent protection for certain of our enoxaparin-related technology and we have sought, and continue to seek to enforce our issued patents.

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. In our development of M356 we filed for patent protection for

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certain of our M356-related technology, and if necessary, we may seek to enforce issued patents relating to our M356 product.

Our follow-on biologics (FOBs) program is targeted toward developing biosimilar and interchangeable versions of marketed biologic therapeutics. 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 opens the market for biosimilar and interchangeable versions of a broad array of biologic therapeutics, including antibodies, cytokines, fusion proteins, hormones and blood factors. Forecasters predict a rapidly growing multi-billion dollar global market for these products. Most of these biologic therapeutics are complex mixtures, and for several years we have been investing in novel approaches to the structural characterization, process engineering and analysis of biologic systems. In February 2012, FDA released three documents containing their preliminary guidelines for applications under the Section 351(k) pathway. These guidelines confirmed that FDA will use a totality-of-the-evidence approach that puts a substantial emphasis on extensive structural and functional characterization in evaluating biosimilar products for approval. We believe the FDA guidances provide a framework for our follow-on biologics strategy. Our goal is to engineer biologic therapeutics that will show minimal structural or functional differences from the reference brand product, thereby justifying a more selective and targeted approach to non-clinical and/or human clinical testing to support demonstration of biosimilarity and interchangeability.

Our novel therapeutics program leverages the capabilities and expertise built during the development of our complex generics and FOB program to address unmet clinical needs. Our most advanced efforts have been in the area of polysaccharide mixtures. M402, our novel polysaccharide-based drug candidate, is in development as a potential anti-cancer agent that targets over five different key biological mechanisms involved in cancer progression and metastasis. Our other polysaccharide-based drug candidate, adomiparin, has been engineered to possess what we believe will be an improved therapeutic profile compared with other currently marketed anticoagulants to support the treatment of ACS. We will not move forward with further clinical trials of adomiparin unless we have a partner for the program. We are also seeking to discover and develop additional novel drugs based either on the polysaccharide-based platform or on a biologics, or proteins and monoclonal antibody, platform. We have built significant capabilities in biological characterization and engineering of proteins through our FOB platform that allow us to create unique and novel formulations of protein and antibody drug compositions for specific disease indications. To add to these capabilities, in December 2011, we acquired selected assets of Virdante Pharmaceuticals, Inc. relating to "sialic switch" technology. Sialic acid is a type of sugar modification on selected proteins that is understood to regulate specific biological functions of these proteins. These assets add to our core ability to modify and engineer protein backbones to precisely regulate biological networks and develop novel biologic product candidates.

In November 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. Sandoz N.V. later assigned its rights in the 2003 Sandoz Collaboration to Sandoz 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, each with Novartis Pharma AG, and a collaboration and license agreement, or the Definitive Agreement, with Sandoz AG, an affiliate of Novartis Pharma AG. Together, this series of agreements is referred to as the 2006 Sandoz Collaboration. Under the Definitive Agreement, we and Sandoz AG jointly develop, manufacture and commercialize M356. 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.

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Prior to the launch of enoxaparin sodium injection, our revenue had been derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and primarily consisted of amounts earned by us for reimbursement by Sandoz of research and development services and development costs for certain programs. 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 is one or more third-party competitors 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 us 45% of the contractual profits from the sale of enoxaparin sodium injection. 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 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, and then a profit share, which occurred in late December 2011. Additionally, in October 2011, FDA approved the ANDA for the enoxaparin product of Watson Pharmaceuticals, Inc., or Waston, and Amphastar Pharmaceuticals, Inc. or 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 U.S. District Court, Watson announced that they and Amphastar intended to launch their enoxaparin product. Consequently, in each product year, for net sales up to a pre-defined sales threshold, Sandoz is obligated to pay us a royalty on net sales, which is payable at a 10% rate, and for net sales above the sales threshold, increases to 12%.

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 in each of the next four years, but the amount of any future payment due to the annual adjustment is not expected to be material.

In December 2011, we entered into a global collaboration with Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, collectively Baxter, to develop and commercialize up to six FOBs, which became effective in February 2012. Baxter is an established healthcare company with global product development, manufacturing and commercial capabilities. To accelerate efforts in the FOB space and address this growing global market, we expect to significantly increase the headcount and related operating expenses dedicated to our FOB program in 2012 and 2013. We expect that the increase in operating expenses will be offset in future years by revenues from option fees and milestone payments under the Baxter collaborative agreement, subject to achievement of technical criteria.

As of December 31, 2011, we had an accumulated deficit of $103.4 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 the commercial sale of enoxaparin sodium injection. Due to the launch of a competitor's enoxaparin sodium injection product in January 2012, our product revenue will decrease. Depending on the future outcome of enoxaparin litigation, we may incur annual operating losses over the next several years as we expand our drug commercialization, development and discovery efforts. Additionally, we plan to continue to evaluate possible acquisitions or licensing of rights to additional technologies, products or

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assets that fit within our growth strategy. Accordingly, we will need to generate significant revenue to maintain profitability.

Financial Operations Overview

Years Ended December 31, 2011, 2010 and 2009

Collaboration Revenue

Collaboration revenue for 2011 was $283.1 million, compared with $116.8 million for 2010 and $20.2 million for 2009.

Collaboration revenue is summarized as follows (in thousands):

	For the Years Ended December 31,		
	2011	**2010**	**2009**
Collaboration revenues:			
Product revenue:			
Profit share/royalty revenue	$ 260,473	$ 96,625	$
Commercial milestone revenue	10,000		
Total product revenue	270,473	96,625	
Research and development revenue:			
Regulatory milestone revenue		5,000	
Research and development revenue	12,595	15,147	20,249
Total research and development revenue	12,595	20,147	20,249
Total collaboration revenue	$ 283,068	$ 116,772	$ 20,249

Profit share/royalty revenue includes revenue earned from Sandoz on sales of enoxaparin sodium injection following its commercial launch in July 2010. 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 is one or more third-party competitors 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 us 45% of the contractual profits from the sale of enoxaparin sodium injection. 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 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 and then a profit share, which occurred in late December 2011. Additionally, in October 2011, FDA approved the ANDA for the enoxaparin product of Watson 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 U.S. District Court, Watson announced that they and Amphastar intended to launch their enoxaparin product. Consequently, in each product year, for net sales up to a pre-defined sales threshold, Sandoz is obligated to pay us a royalty on net sales, which is payable at a 10% rate, and for net sales above the sales threshold, increases to 12%.

For the year ended December 31, 2011, we recorded revenue of $10.0 million due to the achievement of a commercial milestone under the 2003 Sandoz Collaboration as a result of enoxaparin sodium injection reaching the one-year anniversary from launch as the sole generic on the market.

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Research and development revenue for the periods shown consists of amounts earned by us under the 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs, and amounts earned by us under the 2006 Sandoz Collaboration for amortization of the equity premium, reimbursement of research and development services and reimbursement of development costs. For the year ended December 31, 2010, we recorded revenue of $5.0 million due to the achievement of a regulatory milestone under the 2003 Sandoz Collaboration related to FDA's approval of the enoxaparin sodium injection ANDA.

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 will not be indicative of future enoxaparin sodium injection product revenue.

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, 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 2011 was $64.7 million, compared with $51.7 million in 2010 and $60.6 million in 2009. The increase of $13.0 million, or 25%, from the 2010 period to the 2011 period resulted from a $4.5 million in-process research and development charge related to our purchase of assets from Virdante and increases of: $2.0 million in facility-related expenses, principally due to the 2010 lease extension for our headquarters for an additional term of 48 months; $1.6 million in personnel and related costs associated with our headcount growth to support our programs; $1.4 million in process development and third-party research costs in support of our novel drug discovery program; $1.2 million in laboratory expenses; $1.1 million in depreciation and amortization expense primarily due to the amortization related to a milestone payment made during 2011 made with respect to our 2007 asset purchase from Parivid; $1.0 million in consulting fees related to our M356 and novel drug discovery programs; and $0.8 million in share-based compensation expense principally associated with our 2011 employee-wide grant of performance-based restricted stock. These increases were offset by a decrease of $0.8 million in preclinical costs related to our M402 program.

The decrease of $8.9 million, or 15%, from 2009 to 2010 resulted from decreases of: $5.9 million in process development, manufacturing and third-party research costs in support of our development programs, principally our M356 program; $2.3 million in consultant costs and $1.8 million in clinical development costs both of which were associated with the completion in July 2009 of the Phase 2a clinical trial for our adomiparin program; $1.1 million in laboratory expenses related to our enoxaparin sodium injection program; $0.5 million in depreciation expense and facility related expense and $0.3 million in share-based compensation expense. These decreases were offset by increases of $2.5 million in personnel and related costs primarily due to performance payments made in connection with the approval and launch of enoxaparin sodium injection in July 2010 and a $0.5 million credit to research and development expense as a result of a revision to an accrued milestone liability in 2009.

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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. We expect future research and development expenses to increase in support of our product candidates.

The following table summarizes the primary components of our research and development expenditures for our principal commercial and development programs for the years ended December 31, 2011, 2010 and 2009, and it shows the total external costs (including amortization) incurred by us for each of our major commercial and development projects. The table excludes costs incurred by our collaborative partner on such major commercial and development projects. We do not maintain or evaluate, and therefore do not allocate, internal research and development costs on a project-by-project basis. Consequently, we do not analyze internal research and development costs by project in managing our research and development activities.

	Research and Development Expense (in thousands)			
Commercial and Development Programs (Status)	**2011**	**2010**	**2009**	**Project Inception to December 31, 2011**
Enoxaparin sodium injection (ANDA approved July 2010)	$ 2,789	$ 2,093	$ 4,564	$ 49,960
M356 (ANDA Filed)	6,618	7,389	10,670	40,682
Adomiparin (Phase 2a)	94	462	5,641	35,825
Other development programs	4,133	4,197	1,969	
Discovery programs	6,698	332	455	
Research and development internal costs	44,325	37,239	37,313	
Total research and development expense	$ 64,657	$ 51,712	$ 60,612	

The increase of $0.7 million in external expenditures for enoxaparin sodium injection from the 2010 period to the 2011 period was primarily due to an increase in amortization expense related to a milestone payment with respect to our 2007 asset purchase from Parivid made in 2011 offset by a shift to commercial activity being contracted directly with Sandoz. The decrease of $0.8 million in M356 external expenditures from the 2010 period to the 2011 period was primarily due to timing of process development activities, manufacturing and third-party research costs. The decrease of $0.4 million in adomiparin external expenditures from the 2010 period to the 2011 period was due to reduction in spend on this program in 2011. Other development program spend remained consistent from the 2010 period to the 2011 period due to process development on our M402 program. The increase of $6.4 million in the discovery programs was primarily due to a $4.5 million in-process research and development expense related to our purchase of assets from Virdante and an increase in external services and research collaborations associated with our discovery programs.

The research and development internal costs consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation. The increase of $7.1 million from the 2010 period to the 2011 period, was due to additional research and development headcount and related costs in support of our development programs.

The decrease of $2.5 million in external expenditures for enoxaparin sodium injection from the 2009 period to the 2010 period was primarily due to decreased manufacturing activity and a shift to commercial activity being contracted directly with Sandoz. The decrease of $3.3 million in M356

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external expenditures from the 2009 period to the 2010 period was primarily due to the timing of process development activities, manufacturing and third-party research costs. The decrease of $5.2 million in adomiparin external expenditures from the 2009 period to the 2010 period was due to the completion of our Phase 2a clinical trial in June 2009. The increase of $2.2 million in the other development programs from the 2009 period to the 2010 period primarily related to an increase in M402 manufacturing, preclinical and toxicology work.

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, 2011 was $38.7 million, compared to $28.6 million in 2010 and $23.8 million in 2009. General and administrative expense increased by $10.1 million, or 35%, from the 2010 period to the 2011 period due to increases of: $4.8 million in royalty and license fees payable primarily to Massachusetts Institute of Technology associated with the sales of enoxaparin sodium injection and milestones earned by us related to enoxaparin sodium injection; $3.8 million in professional fees principally due to increased legal fees relating to enoxaparin litigation; $0.5 million in personnel and related costs associated with our headcount growth; $0.5 million in facility-related expenses principally due to the 2010 lease extension for our headquarters for an additional term of 48 months; and $0.5 million in consulting activities.

General and administrative expense increased by $4.8 million, or 20%, from the 2009 period to the 2010 period due to increases of: $1.8 million in royalty and license fees payable to Massachusetts Institute of Technology associated with the launch and sales of enoxaparin sodium injection; $1.5 million in professional and other fees primarily due to an increase in legal and consulting activities; $1.1 million in personnel and related costs primarily due to performance payments made in connection with the approval and launch of enoxaparin sodium injection in July 2010; and a $0.4 million increase in share-based compensation expense.

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

Interest Income

Interest income was $0.7 million, $0.2 million and $0.8 million for the years ended December 31, 2011, 2010 and 2009, respectively. The increase of $0.5 million from the 2010 period to the 2011 period was primarily due to higher average investment balances because we earned significant product revenue from Sandoz during 2011. The decrease of $0.6 million from the 2009 period to the 2010 period was primarily due to lower average investment balances and lower interest rates.

Interest Expense

Interest expense was $0.1 million, $0.3 million and $0.6 million for the years ended December 31, 2011, 2010 and 2009, respectively. The decrease of $0.2 million from the 2010 period to the 2011 period and the decrease of $0.3 million from the 2009 period to the 2010 period were primarily due to the completion of repayment schedules on our equipment line of credit during 2011 and 2010.

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Other Income (Expense)

Other income of $1.0 million for the year ended December 31, 2010 was due to the receipt of a tax grant related to the approval of our application for the Qualifying Therapeutic Discovery Project program during 2010.

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 $405.9 million through private and public issuance of equity securities, including the issuance of shares to Novartis Pharma AG in connection with our 2006 Sandoz Collaboration. As of December 31, 2011, we have received a cumulative total of $471.5 million from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, $4.0 million from debt financing, $9.2 million from capital lease obligations and $3.2 million from our landlord for leasehold improvements related to our corporate facility and additional funds from interest income. The fact that we and Sandoz are no longer the sole generic competitor to Lovenox, and we currently receive and will continue to receive a royalty based on net sales of enoxaparin sodium injection has had and will have a negative impact on our near term cash generation trend. We expect to finance our current 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 2014. 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 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, 2011, we had $348.4 million in cash, cash equivalents and marketable securities and $28.2 million in accounts receivable. In addition, we also held $17.5 million in restricted cash which serves as collateral for a security bond posted in the litigation against Watson Pharmaceuticals Inc., Amphastar Pharmaceuticals Inc. and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar). Our funds at December 31, 2011 were primarily invested in senior debt of government-sponsored enterprises, commercial paper, 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 risk at December 31, 2011.

During the year ended December 31, 2011, our operating activities provided cash of $213.7 million. During the years ended December 31, 2010 and 2009, our operating activities used $1.1 million and $55.3 million of cash, respectively. The cash provided by or used for operating activities generally approximates our net income (loss) adjusted for non-cash items and changes in operating assets and liabilities.

For the year ended December 31, 2011, our net income adjusted for non-cash items was $203.4 million. For the year ended December 31, 2011, non-cash items include share-based compensation of $11.1 million, purchase of assets from Virdante 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

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$10.3 million and resulted from: a decrease in accounts receivable of $26.3 million, due to a decrease in net sales of enoxaparin by Sandoz, due primarily to lower unit pricing, and by a contractual change in the basis of calculating our enoxaparin 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 to maintain the preliminary injunction; 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.

For the year ended December 31, 2010, our net income adjusted for non-cash items was $53.8 million. For the year ended December 31, 2010, non-cash items include share-based compensation of $10.8 million and depreciation and amortization of property and equipment and intangible assets of $4.7 million. In addition, the net change in our operating assets and liabilities used cash of $54.8 million and resulted from: an increase in accounts receivable of $54.5 million, primarily due to the timing of cash receipts from Sandoz related to our share of Sandoz's profit from sales of enoxaparin sodium injection during the third and fourth quarters of 2010; an increase in unbilled revenue of $0.5 million, resulting from increased manufacturing costs for M356; an increase in accrued expenses of $3.0 million, due to an accrual for royalties payable to MIT based on our share of Sandoz's profit from sales of enoxaparin sodium injection during the third and fourth quarters of 2010 and an increase in the bonus pool for 2010-related performance; and a decrease in deferred revenue of $2.9 million, principally due to the amortization of the $13.6 million equity premium paid by Novartis in connection with the 2006 Sandoz Collaboration.

For the year ended December 31, 2009, our net loss adjusted for non-cash items was $48.4 million. In addition, the net change in our operating assets and liabilities used cash of $6.9 million and resulted from: a decrease in accounts receivable of $0.5 million, due to the timing of cash receipts from Sandoz related to reimbursement of research and development services and reimbursement of development costs; an increase in unbilled collaboration revenue of $2.4 million, resulting from increased commercial activities for our M356 program; an increase in prepaid expenses and other current assets of $0.5 million, related to interest accrued on U.S. Treasury and government-sponsored enterprise securities; a decrease in accounts payable of $1.4 million, primarily due to the timing of manufacturing costs for M356 manufacturing; a decrease in accrued expenses of $0.6 million, due to a decrease in clinical accruals associated with the completion in June 2009 of our Phase 2a clinical trial for our adomiparin program; a decrease in deferred revenue of $1.5 million, principally due to the amortization of the $13.6 million equity premium paid by Novartis in connection with the 2006 Sandoz Collaboration; and a decrease in other current liabilities of $2.0 million. Of the $2.0 million decrease in other current liabilities, $0.5 million relates to a revision to an accrued milestone liability, $0.5 million was paid in cash and $1.0 million of common stock was issued as consideration for the completion and satisfaction of milestones achieved under our asset purchase agreement with Parivid LLC.

Net cash used in investing activities was $268.7 million for the year ended December 31, 2011. During 2011, we used $551.2 million of cash to purchase marketable securities and we received $302.4 million from maturities of marketable securities. Additionally, during 2011, we paid Parivid $6.7 million as consideration for the completion and satisfaction of a milestone related to our enoxaparin sodium injection developed technology and purchased assets from Virdante of $4.5 million. Net cash provided by investing activities was $19.1 million for the year ended December 31, 2010. During 2010, we used $90.8 million of cash to purchase marketable securities and we received $111.5 million from maturities of marketable securities. Net cash used in investing activities was $22.3 million for the year ended December 31, 2009. During 2009, we used $110.2 million of cash to purchase marketable securities and we received $89.6 million from maturities of marketable securities. During the years ended December 31, 2011, 2010 and 2009, we used $8.7 million, $1.7 million and $1.7 million, respectively, to purchase laboratory equipment and leasehold improvements.

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Net cash provided by financing activities was $3.6 million, $60.7 million and $44.4 million for the years ended December 31, 2011, 2010 and 2009, respectively. During 2011, we received net proceeds of $5.5 million from stock option exercises and purchases of common shares through our employee stock purchase plan. 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 corporate facility. During 2010, we received net proceeds of $57.1 million from our public offering of common stock and $6.7 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of $2.3 million on our capital lease agreement obligations and $0.7 million on financed leasehold improvements related to our corporate facility. During 2009, we received net proceeds of $46.8 million from our public offering of common stock and $0.5 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of $2.2 million on our line of credit and capital lease agreement obligations and $0.7 million on financed leasehold improvements related to our corporate facility.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2011:

Contractual Obligations (in thousands)	Total	2012	2013 through 2014	2015 through 2016	After 2016
License maintenance obligations	$ 788	$ 158	$ 315	$ 315	*
License royalty obligations	1,425	325	600	500	*
Operating lease obligations	19,419	6,995	10,812	1,612	$
Total contractual obligations	$ 21,632	$ 7,478	$ 11,727	$ 2,427	$

*

After 2016, the annual obligations, which extend through the life of the patent are approximately $0.4 million per year.

As a result of generating U.S. taxable income during the years ended December 31, 2011 and 2010, we utilized $192.3 million and $26.3 million, respectively, of our available net operating loss carryforwards to offset this income. Accordingly, we will carry minimal net operating loss carryforwards into 2012 to offset future net taxable income, if any. Our ability to generate taxable income in 2012 depends on the outcome of the enoxaparin litigation.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. 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.

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Revenue Recognition

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

To date, we have received revenue from collaboration agreements with one collaborative partner. 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, milestone payments if specified objectives are achieved and/or profit-sharing or royalties on product sales. Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). The consideration received is then allocated among the separate units based on either their respective fair values or the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

In January 2011, we adopted Financial Accounting Standards Board's, or FASB, Accounting Standards Update, or ASU, No. 2009-13, "*Multiple-Deliverable Revenue Arrangements (Topic 615)*," or ASU 2009-13, on a prospective basis 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.

Pursuant to ASU 2009-13, each required deliverable is evaluated 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 limited to the consideration not contingent upon future deliverables.

For multiple-element arrangements entered into prior to January 1, 2011 and not materially modified thereafter, we continue to apply its prior accounting policy with respect to such arrangements. Under this policy, in general, revenue from non-refundable, upfront fees related to intellectual property rights/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. This requirement with respect to the fair value of undelivered items was modified in the newly issued accounting standard. Research and development funding is recognized as earned over the period of effort. In general, the consideration with respect to the other deliverables is recognized when the goods or services are delivered.

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We have research, collaboration and license agreements related to the development and commercialization of product candidates pursuant to which we could receive consideration in the form of milestone payments in future periods. In January 2011, we adopted ASU No. 2010-17, "*Revenue Recognition Milestone Method*," or ASU 2010-17, on a prospective basis for all sales-based, commercial and research and development milestones achieved. Pursuant to ASU 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 substantive 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 (1) 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, (2) the consideration relates solely to past performance and (3) 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 our existing research and development arrangements are substantive. Revenues from development and regulatory milestones, if they are nonrefundable 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 our accounting policy for multiple element arrangements. 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

We have certain financial assets recorded at fair value which have been classified as Level 1 or 2 within the fair value hierarchy as described in the accounting standards for fair value measurements. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the measurement of fair value. The three levels of the hierarchy are defined as follows:

Level 1 Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 Fair values are determined by utilizing quoted prices for identical or similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves; and

Level 3 Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

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,

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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, 2011 and December 31, 2010.

The carrying amounts reflected in the 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. The carrying amounts of the capital lease obligations approximate their fair values due to their variable interest rates.

Marketable Securities

Available-for-sale debt securities are recorded at fair market value. Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. We determine the appropriate classification of our investments in marketable securities at the time of purchase and evaluate such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive income (loss), which is reported as a separate component of stockholders' equity. If a decline in the fair value is considered other-than-temporary, based on available evidence, the unrealized loss is transferred from other comprehensive income (loss) to the statements of operations. There were no charges taken for other than temporary declines in fair value of marketable securities in 2011, 2010 or 2009. Realized gains and losses are reported in interest income on a specific identification basis. There were no realized gains or losses on marketable securities during the years ended December 31, 2011, 2010 or 2009.

Fair Value of Other Financial Instruments

The carrying amounts of our financial instruments that are not stated at fair value, which include accounts receivable, unbilled collaboration revenue and other accrued expenses, approximate their fair values due to their short maturities. The carrying amount of our line of credit and capital lease obligations approximate their fair values due to their variable interest rates.

Intangible Assets

We have acquired intangible assets that we value and record. We use a discounted cash flow model to value intangible assets at acquisition. The discounted cash flow model requires assumptions about the timing and amount of future cash inflows and outflows, risk and the cost of capital. Each of these factors can significantly affect the value of the intangible asset. We review intangible assets for impairment on a periodic basis using an undiscounted net cash flows approach when impairment indicators arise. If the undiscounted cash flows of an intangible asset are less than the carrying value of an intangible asset, we would write down the intangible asset to the discounted cash flow value. Where we cannot identify cash flows for an individual asset, our review is applied at the lowest group level for which cash flows are identifiable.

Share-Based Compensation Expense

We recognize the fair value of share-based compensation in our statement of operations. Share-based compensation expense primarily relates to stock options, restricted stock and stock issued under our stock option plans and employee stock purchase plan. We recognize 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 the requisite service period. We issue new shares to

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satisfy stock option exercises, the issuance of restricted stock and stock issued 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. Option valuation models require the input of highly subjective assumptions, including stock price volatility and expected term of an option. We believe a blended volatility rate based upon historical performance, as well as the implied volatilities of currently traded options, best reflects the expected volatility of our stock going forward. 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 employee exercise and post-vest termination behavior and expected term data from our peer group to arrive at the estimated expected life of an option. We update these assumptions as needed to reflect recent historical data. Additionally, we are required to estimate forfeiture rates to approximate the number of shares that will vest in a period to which the fair value is applied. Estimated forfeitures will be adjusted to actual forfeitures upon the vest date of the cancelled options as a cumulative adjustment on a quarterly basis.

The value of our restricted stock awards is recognized as compensation cost in our consolidated statements of operations over each award's explicit or implicit service periods. We estimate an award's implicit service period based on our best estimate of the period over which an award's vesting conditions will be achieved. We reevaluate 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.

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 2004, except to the extent that in the future we utilize net operating losses or tax credit carryforwards that originated before 2004. Currently we are not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

Related Party Transactions

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. Parivid was considered to be a related party as a co-founder and then-member of our Board of Directors is the brother of S. Raguram. Pursuant to the Purchase Agreement, we 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

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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 2007, we 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, 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 the parties 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 the 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 the consolidated balance sheet as of December 31, 2011. The developed technology is being amortized over the estimated useful life of the enoxaparin sodium injection developed technology of approximately 10 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, 2011, 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.

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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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2012 expressed an unqualified opinion thereon.

/s/
Ernst &
Young LLP

Boston, Massachusetts
February 28, 2012

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Momenta Pharmaceuticals, Inc.

Consolidated Balance Sheets

(In thousands, except per share amounts)

	December 31,	
	2011	**2010**
Assets		
Current assets:		
Cash and cash equivalents	$ 49,245	$ 100,681
Marketable securities	299,193	52,078
Accounts receivable	28,171	54,485
Unbilled revenue	2,765	5,265
Prepaid expenses and other current assets	2,547	1,793
Restricted cash	17,500	
Total current assets	399,421	214,302
Property and equipment, net of accumulated depreciation	13,327	9,003
Intangible assets, net	7,772	2,486
Restricted cash		1,778
Other long term assets	389	
Total assets	$ 420,909	$ 227,569
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,709	$ 4,394
Accrued expenses	9,131	9,098
Deferred revenue	2,156	2,150
Capital lease obligations		1,729
Lease financing liability		258
Deferred rent	32	23
Total current liabilities	16,028	17,652
Deferred revenue, net of current portion	1,608	3,763
Deferred rent, net of current portion	144	
Other long term liabilities	51	51
Total liabilities	17,831	21,466
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Preferred stock, $0.01 par value; 5,000 shares authorized at December 31, 2011 and 2010, 100 shares of Series A Junior Participating Preferred Stock, $0.01 par value designated and no shares issued and outstanding		
Common stock, $0.0001 par value; 100,000 shares authorized at December 31, 2011 and 2010, 51,285 and 49,747 shares issued and outstanding at December 31, 2011 and 2010, respectively	5	5
Additional paid-in capital	506,557	489,873
Accumulated other comprehensive loss	(81)	(16)
Accumulated deficit	(103,403)	(283,759)
Total stockholders' equity	403,078	206,103
Total liabilities and stockholders' equity	$ 420,909	$ 227,569

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

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Momenta Pharmaceuticals, Inc.

Consolidated Statements of Operations

(In thousands, except per share amounts)

	Year Ended December 31,		
	2011	**2010**	**2009**
Collaboration revenues:			
Product revenue	$ 270,473	$ 96,625	$
Research and development revenue	12,595	20,147	20,249
Total collaboration revenue	283,068	116,772	20,249
Operating expenses:			
Research and development*	64,657	51,712	60,612
General and administrative*	38,710	28,595	23,800
Total operating expenses	103,367	80,307	84,412
Operating income (loss)	179,701	36,465	(64,163)
Other income (expense):			
Interest income	746	176	825
Interest expense	(91)	(329)	(570)
Other income (expense)		978	(104)
Total other income	655	825	151
Net income (loss)	$ 180,356	$ 37,290	$ (64,012)
Net income (loss) per share:			
Basic	$ 3.62	$ 0.84	$ (1.60)
Diluted	$ 3.55	$ 0.81	$ (1.60)
Weighted average shares outstanding:			
Basic	49,852	44,626	40,056
Diluted	50,823	45,942	40,056
* Includes the following share-based compensation expense:			
Research and development	$ 4,919	$ 4,085	$ 4,377
General and administrative	$ 6,219	$ 6,755	$ 6,378

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

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Momenta Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity And Comprehensive Income (Loss)

(In thousands)

	Common Stock Shares	Common Stock Par Value	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2008	39,691	$ 4	$ 356,124	$ 414	$ (257,037)	$ 99,505
Issuance of common stock in public offering	4,600		46,766			46,766
Issuance of common stock to Parivid	91		1,000			1,000
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	76		569			569
Issuance of restricted stock	169					
Share-based compensation expense for employees			10,658			10,658
Share-based compensation expense for non-employee			97			97
Unrealized loss on marketable securities				(421)		(421)
Net loss					(64,012)	(64,012)
Comprehensive loss						(64,433)
Balances at December 31, 2009	44,627	$ 4	$ 415,214	$ (7)	$ (321,049)	$ 94,162
Issuance of common stock in public offering	4,218	1	57,084			57,085
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	794		6,735			6,735
Issuance of restricted stock	147					
Cancellation of restricted stock	(39)					
Share-based compensation expense for employees			10,361			10,361
Share-based compensation expense for non-employees			479			479
Unrealized loss on marketable securities				(9)		(9)
Net income					37,290	37,290
Comprehensive income						37,281
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
Comprehensive income						180,291
Balances at December 31, 2011	51,285	$ 5	$ 506,557	$ (81)	$ (103,403)	$ 403,078

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

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Momenta Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2011	**2010**	**2009**
Cash Flows from Operating activities:			
Net income (loss)	$ 180,356	$ 37,290	$ (64,012)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
In-process research and development expense	4,500		
Depreciation and amortization	4,137	4,361	4,470
Share-based compensation expense	11,138	10,840	10,755
Amortization of premium (accretion of discount) on investments	1,677	893	(57)
Amortization of intangibles	1,378	299	326
Loss on disposal of assets	238	102	114
Changes in operating assets and liabilities:			
Accounts receivable	26,314	(54,485)	455
Unbilled revenue	2,500	(515)	(2,378)
Prepaid expenses and other current assets	(754)	(100)	(476)
Restricted cash	(15,722)		
Other assets	(389)		12
Accounts payable	315	169	(1,353)
Accrued expenses	33	2,984	(630)
Deferred rent	153	(70)	(70)
Deferred revenue	(2,149)	(2,850)	(1,450)
Other current liabilities			(1,000)
Other long term liabilities		25	
Net cash provided by (used in) operating activities	213,725	(1,057)	(55,294)
Cash Flows from Investing activities:			
Purchase of assets from Virdante	(4,500)		
Purchases of property and equipment	(8,699)	(1,671)	(1,654)
Purchases of marketable securities	(551,272)	(90,765)	(110,194)
Proceeds from maturities of marketable securities	302,415	111,501	89,575
Milestone payment related to developed technology	(6,664)		
Net cash (used in) provided by investing activities	(268,720)	19,065	(22,273)
Cash Flows from Financing activities:			
Proceeds from public offering of common stock, net of issuance costs		57,085	46,766
Proceeds from issuance of common stock under stock plans	5,546	6,735	569
Payments on financed leasehold improvements	(258)	(737)	(687)
Principal payments on capital lease obligations	(1,729)	(2,344)	(2,200)
Principal payments on line of credit			(17)
Net cash provided by financing activities	3,559	60,739	44,431
(Decrease) increase in cash and cash equivalents	(51,436)	78,747	(33,136)
Cash and cash equivalents, beginning of period	100,681	21,934	55,070
Cash and cash equivalents, end of period	$ 49,245	$ 100,681	$ 21,934

Supplemental Cash Flow Information:			
Cash paid for interest	$ 91	$ 329	$ 570
Supplemental Non-Cash Information:			
Issuance of common stock for payment of Parivid milestone	$	$	$ 1,000

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

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Momenta Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements December 31, 2011

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 detailed structural analysis of complex mixture drugs, applying its technology to the development of generic or follow-on versions of complex drug products as well as to the discovery and development of complex novel drugs. The Company presently derives all of its revenue from one collaborative partner. Collaboration revenue consists of product revenue related to the profit-sharing or royalties related to sales of enoxaparin sodium injection, milestones, and reimbursement of research and development expenses.

2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

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

Reclassifications

Certain prior year amounts in marketable securities have been reclassified from long-term assets to current assets to conform to the current year presentation.

Revenue Recognition

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

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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

Through early 2012, the Company received revenue from collaboration agreements with one collaborative partner. 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, milestone payments if specified objectives are achieved and/or profit-sharing or royalties on product sales. Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). The consideration received is then allocated among the separate units based on either their respective fair values or the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

In January 2011, the Company adopted Financial Accounting Standards Board's ("FASB") Accounting Standards Update ("ASU") No. 2009-13, "*Multiple-Deliverable Revenue Arrangements (Topic 615)*" ("ASU 2009-13") on a prospective basis 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 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 2009-13, each required deliverable is evaluated 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 ("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 limited to the consideration not contingent upon future deliverables.

For multiple-element arrangements entered into prior to January 1, 2011 and not materially modified thereafter, the Company continues to apply its prior accounting policy with respect to such arrangements. Under this policy, in general, revenue from non-refundable, upfront fees related to intellectual property rights/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. This requirement with respect to the fair value of undelivered items was modified in the newly issued accounting standard. Research and development funding is recognized as earned over the period of effort. In general, the consideration with respect to the other deliverables is recognized when the goods or services are delivered.

The Company has research, collaboration and license agreements with Sandoz AG and Sandoz Inc. (collectively referred to as Sandoz), related to the development and commercialization of enoxaparin sodium injection and generic Copaxone (referred to as M356) pursuant to which it could receive consideration in the form of milestone payments in future periods. In January 2011, the Company adopted ASU No. 2010-17, "*Revenue Recognition Milestone Method*" (ASU 2010-17) on a prospective basis for all sales-based, commercial and research and development milestones achieved. In accordance

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with ASU 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 the Company's performance, (b) there is substantive 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 (1) 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 the Company's performance to achieve the milestone, (2) the consideration relates solely to past performance and (3) 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 all of the development and regulatory milestones pursuant to its 2003 Sandoz Collaboration and 2006 Sandoz Collaboration are substantive. Revenues from development and regulatory milestones, if they are nonrefundable 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 the Company's accounting policy for multiple element arrangements. 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 and Cash Equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash and that mature within three months from date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and were primarily comprised of money market funds at December 31, 2011.

Fair Value Measurements

The Company has certain financial assets recorded at fair value which have been classified as Level 1 or 2 within the fair value hierarchy as described in the accounting standards for fair value measurements. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the measurement of fair value. The three levels of the hierarchy are defined as follows:

Level 1 Fair values are determined utilizing quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 Fair values are determined by utilizing quoted prices for identical or similar assets and liabilities in active markets or other market observable inputs such as interest rates and yield curves; and

Level 3 Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, unbilled revenue, other current assets, accounts payable and accrued expenses approximate fair value

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due to their short-term maturities. The carrying amounts of the capital lease obligations approximate their fair values due to their variable interest rates.

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.

Marketable Securities

Available-for-sale debt securities are recorded at fair market value. Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. The Company determines the appropriate classification of its investments in marketable securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive loss in stockholders' equity unless the security has experienced a credit loss, the Company intends to sell the security or the Company has determined that it is more likely than not that it will have to sell the security before its expected recovery, in which case the unrealized loss would be recognized in results of operations. Realized gains and losses are reported in interest income on a specific identification basis. There were no charges taken for other-than-temporary declines in fair value of marketable securities and no realized gains or losses on marketable securities during the years ended December 31, 2011, 2010 or 2009.

Accounts Receivable and Unbilled Revenue

Accounts receivable represents amounts due to the Company at December 31, 2011 and December 31, 2010 from one collaborative partner related to sales of enoxaparin sodium injection and reimbursement of research and development expenses. Unbilled revenue represents amounts owed at December 31, 2011 and December 31, 2010 from the same collaborative partner for reimbursement of research and development expenses. The Company has not recorded any allowance for uncollectible accounts or bad debt write-offs and it monitors its receivables to facilitate timely payment.

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

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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, 2011.

Research and Development

Research and development costs are expensed as incurred. Research and development costs include salaries and related expenses for personnel, license fees, consulting fees, nonclinical and clinical trial costs, contract research and manufacturing costs, and the costs of laboratory equipment and facilities.

Non-refundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are received.

Share-Based Compensation Expense

The Company recognizes the fair value of share-based compensation in its consolidated statements of operations. Share-based compensation expense primarily relates to stock options, restricted stock and stock issued under the Company's 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 conditions 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 the Company's 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 the Company's stock, the expected term of the award and the expected forfeiture rate associated with the Company's stock option plans. The Company considers, among other factors, the implied volatilities of its own currently traded options to provide an estimate of volatility based upon current trading activity. The Company uses a blended volatility rate based upon its own historical performance, as well as the implied volatilities of its own currently traded options, as it believes this appropriately reflects the expected volatility of its stock. 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.

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Unvested stock options held by consultants are revalued using the Company's estimate of fair value at each balance sheet date.

Net Income (Loss) Per Share

The Company computes basic net income (loss) per share by dividing net income (loss) by the weighted average number of 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. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted average number of shares and potential shares from outstanding stock options and unvested restricted stock determined by applying the treasury stock method. For the year ended December 31, 2009, the effect of all potentially dilutive securities is anti-dilutive as the Company had a net loss for that period. Accordingly, basic and diluted net loss per share is the same for the year ended December 31, 2009.

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 2004, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2004. The Company currently is not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

Comprehensive Income (Loss)

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

The Company's total comprehensive income (loss) consists of the following (in thousands):

	For the Years Ended December 31,		
	2011	**2010**	**2009**
Net income (loss)	$ 180,356	$ 37,290	$ (64,012)
Other comprehensive loss:			
Unrealized losses on available-for-sale securities	(65)	(9)	(421)
Comprehensive income (loss)	$ 180,291	$ 37,281	$ (64,433)

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Segment Reporting

Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance. The Company has only one operating segment, the discovery, development and commercialization of pharmaceutical products. All of the Company's revenues through December 31, 2011 have come from one collaborative partner and are based solely on activities in the United States.

Recently Issued Accounting Standards

In December 2011, the FASB issued ASU No. 2011-11, "*Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities*" ("ASU 2011-11"). This newly issued accounting standard requires an entity to disclose both gross and net information about instruments and transactions eligible for offset in the statement of financial position as well as instruments and transactions executed under a master netting or similar arrangement and was issued to enable users of financial statements to understand the effects or potential effects of those arrangements on its financial position. This ASU is required to be applied retrospectively and is effective for fiscal years, and interim periods within those years, beginning on or after January 1, 2013. As this accounting standard only requires enhanced disclosure, the adoption of this standard is not expected to have an impact on the Company's financial position or results of operations.

In June 2011, the FASB issued ASU No. 2011-05, "*Comprehensive Income (Topic 220): Presentation of Comprehensive Income*" ("ASU 2011-05"). This newly issued accounting standard (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this ASU do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor do the amendments affect how earnings per share is calculated or presented. In December 2011, the FASB issued ASU No. 2011-12, "*Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*", which defers the requirement within ASU 2011-05 to present on the face of the financial statements the effects of reclassifications out of accumulated other comprehensive income on the components of net income and other comprehensive income for all periods presented. During the deferral, entities should continue to report reclassifications out of accumulated other comprehensive income consistent with the presentation requirements in effect prior to the issuance of ASU 2011-05. These ASUs are required to be applied retrospectively and are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011, which for the Company means January 1, 2012. As these accounting standards do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income, the adoption of these standards is not expected to have an impact on the Company's financial position or results of operations.

In May 2011, the FASB issued ASU No. 2011-04, "*Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*" ("ASU 2011-04"). This newly issued accounting standard clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This ASU is effective on a prospective basis for annual and interim reporting periods beginning on or after December 15, 2011. The Company does not expect that adoption of this standard will have a material impact on its financial position or results of operations.

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3. Fair Value Measurements

The tables below present information about the Company's assets that are measured at fair value on a recurring basis as of December 31, 2011 and December 31, 2010 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*.

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, 2011 and December 31, 2010.

There have been no transfers of assets between the fair value measurement classifications.

The following tables set forth the Company's financial assets that were recorded at fair value at December 31, 2011 and December 31, 2010 (in thousands):

Description	Balance as of December 31, 2011	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 45,316	$ 45,316	$	$
Marketable securities:				
U.S. Government-sponsored enterprise obligations	163,997		163,997	
Corporate debt securities	64,245		64,245	
Commercial paper obligations	66,245		66,245	
Foreign government bond	6,705		6,705	
U.S. Treasury obligation	1,001	1,001		
Total	$ 347,509	$ 46,317	$ 301,192	$

Description	Balance as of December 31, 2010	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 99,911	$ 99,911	$	$
Marketable securities:				
U.S. Government-sponsored enterprise obligations	48,557		48,557	
Corporate debt securities	3,521		3,521	
Total	$ 151,989	$ 99,911	$ 52,078	$

In the tables above, as of December 31, 2011 and December 31, 2010, corporate debt securities include $28.5 million and $3.5 million, respectively, of Federal Deposit Insurance Corporation, or FDIC, guaranteed senior notes issued by financial institutions under the FDIC's Temporary Liquidity Guarantee Program.

The Company did not have any non-recurring fair value measurements on any assets or liabilities at December 31, 2011 and December 31, 2010.

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4. Cash, Cash Equivalents and Marketable Securities

The following tables summarize the Company's cash, cash equivalents and marketable securities as of December 31, 2011 and December 31, 2010 (in thousands):

As of December 31, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 46,245	$	$	$ 46,245
U.S. Government-sponsored enterprise obligations				
Due in one year or less	53,730	10	(4)	53,736
Due in two years or less	110,344	11	(94)	110,261
Corporate debt securities				
Due in one year or less	63,224	12	(48)	63,188
Due in two years or less	1,060		(3)	1,057
Commercial paper obligations due in one year or less	66,193	52		66,245
Foreign government bond due in one year or less	6,722		(17)	6,705
U.S. Treasury obligations due in one year or less	1,001			1,001
Total	$ 348,519	$ 85	$ (166)	$ 348,438
Reported as:				
Cash and cash equivalents	$ 49,244	$ 1	$	$ 49,245
Marketable securities	299,275	84	(166)	299,193
Total	$ 348,519	$ 85	$ (166)	$ 348,438

As of December 31, 2010	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 100,681	$	$	$ 100,681
U.S. Government-sponsored enterprise obligations				
Due in one year or less	37,574	2	(15)	37,561
Due in two years or less	10,996	3	(3)	10,996
Corporate debt securities due in one year or less	3,524		(3)	3,521
Total	$ 152,775	$ 5	$ (21)	$ 152,759
Reported as:				
Cash and cash equivalents	$ 100,681	$	$	$ 100,681
Marketable securities	52,094	5	(21)	52,078
Total	$ 152,775	$ 5	$ (21)	$ 152,759

At December 31, 2011, the Company held 35 marketable securities that were in a continuous unrealized loss position for less than one year. At December 31, 2010, the Company held 13 marketable securities that were in a continuous unrealized loss position for less than one year. The

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unrealized losses were caused by fluctuations in interest rates. The following table summarizes the aggregate fair value of these securities at December 31, 2011 and December 31, 2010 (in thousands):

	December 31,			
	2011		2010	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
U.S. Government-sponsored enterprise obligations	$ 104,107	$ (98)	$ 37,316	$ (18)
Corporate debt securities	$ 36,582	$ (51)	$ 3,521	$ (3)
Foreign government bond	$ 6,705	$ (17)	$	$

At December 31, 2011 and December 31, 2010, no marketable securities were in a continuous unrealized loss position for greater than one year.

To determine whether an other-than-temporary impairment exists, the Company considers whether it intends to sell the debt security and, if it does not intend to sell the debt security, it considers available evidence to assess whether it is more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. The Company reviewed its investments with unrealized losses and concluded that no other-than-temporary impairment existed at December 31, 2011 as it has the ability and intent to hold these investments to maturity and it is not more likely than not that it will be required to sell the security before the recovery of its amortized cost basis.

5. Property and Equipment

At December 31, 2011 and December 31, 2010, property and equipment, net consists of the following (in thousands):

	December 31,		
	2011	2010	Depreciable Lives
Computer equipment	$ 1,267	$ 638	3 years
Software	4,153	3,280	3 years
Office furniture and equipment	1,652	1,255	5 to 6 years
Laboratory equipment	20,929	12,711	7 years
Leasehold improvements	6,744	4,846	Shorter of asset life or lease term
Equipment purchased under capital lease obligations		4,491	3 to 7 years
Less: accumulated depreciation	(21,418)	(18,218)	
	$ 13,327	$ 9,003	

Depreciation and amortization expense, including amortization of assets recorded under capital leases, amounted to $4.1 million, $4.4 million and $4.5 million for the years ended December 31, 2011, 2010 and 2009, respectively.

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6. Intangible Assets

As of December 31, 2011 and December 31, 2010, intangible assets, net of accumulated amortization, are as follows (in thousands):

	Weighted-Average Amortization Period (in years)	December 31, 2011 Gross Carrying Amount	December 31, 2011 Accumulated Amortization	December 31, 2010 Gross Carrying Amount	December 31, 2010 Accumulated Amortization
Core and developed technology	10	$ 10,257	$ (2,485)	$ 3,593	$ (1,107)
Non-compete agreement	2	170	(170)	170	(170)
Total intangible assets	10	$ 10,427	$ (2,655)	$ 3,763	$ (1,277)

The Company's intangible assets are described within Note 16, *Related Party Transactions*.

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 $1.4 million, $0.3 million and $0.3 million during years ended December 31, 2011, 2010 and 2009, 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 $1.8 million as collateral for a letter of credit related to the lease of office and laboratory space located at 675 West Kendall Street, Cambridge, Massachusetts (the "West Kendall Sublease"). This balance remained restricted during the initial 80-month lease term and the 48-month extension term and the Company earned interest on the balance. In 2011, as a result of the expiration and termination of the letter of credit, the restriction lapsed and the $1.8 million is included in cash and cash equivalents in the consolidated balance sheet as of December 31, 2011.

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

8. Accrued Expenses

At December 31, 2011 and December 31, 2010, accrued expenses consisted of the following (in thousands):

	2011	2010
Accrued compensation	$ 5,165	$ 4,387
Accrued contracted research costs	434	2,508
Accrued royalties	2,096	1,437
Accrued professional fees	990	561
Other	446	205
	$ 9,131	$ 9,098

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9. Collaborations and License Agreements

2003 Sandoz Collaboration

In November 2003, the Company entered into a collaboration and license agreement (the "2003 Sandoz Collaboration") with 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 United States Food and Drug Administration, or 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. The Company earned $260.5 million and $96.6 million in profit share/royalty product revenue from Sandoz during the years ended December 31, 2011 and 2010, respectively. 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 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 Watson 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 U.S. District Court, Watson announced that they and Amphastar intended to launch their enoxaparin product. Consequently, in each product year, Sandoz is obligated to pay the Company a royalty on net sales, 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%.

If certain milestones are achieved with respect to enoxaparin sodium injection under certain circumstances, Sandoz agreed to make payments to the Company which would reach $55 million if all

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such milestones are achieved. Under the 2003 Sandoz Collaboration, the Company earned and recognized $5.0 million in research and development revenue in July 2010 upon achievement of a regulatory milestone. In addition, no third-party competitors had marketed a Lovenox-Equivalent Product as of July 23, 2011, the one year anniversary of the FDA's approval of enoxaparin sodium for injection. As a result, for the year ended December 31, 2011, the Company earned and recognized $10.0 million in product revenue upon the achievement of a 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, including an authorized generic Lovenox-Equivalent, 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 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.

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 definitive collaboration and license agreement (as amended, the "Definitive Agreement"). 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. The Company recognizes revenue from the $13.6 million paid premium on a straight-line basis over the estimated development period of approximately six years beginning in June 2007. The Company recognized research and development revenue relating to this paid premium of approximately $2.2 million for each of the years ended December 31, 2011, 2010 and 2009. 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 a generic Copaxone product 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 on a commercially reasonable 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. 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

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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 Definitive 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 Definitive 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. The parties will share profits in varying proportions, depending on the product. 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 that include $10.0 million in regulatory milestones related to the approval by the FDA of M356 and $153.0 million in sales-based and commercial milestones. 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. The Company recorded a reduction in research and development revenue of $1.5 million for the year ended December 31, 2011 related to the shared development costs.

Massachusetts Institute of Technology

The Company has two patent license agreements with the Massachusetts Institute of Technology ("M.I.T.") that grant the Company various exclusive and nonexclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to methods and technologies for analyzing and characterizing sugars and certain heparins, heparinases and other enzymes and synthesis methods. Subject to typical retained rights of M.I.T. and the United States government, the Company was granted exclusive rights under certain of these patents and applications in certain fields.

The Company must meet certain diligence requirements in order to maintain the licenses under the two agreements. Under the agreements, the Company must expend at least $1.0 to $1.2 million per year towards the research, development and commercialization of products and processes covered by the agreements. In addition, the Company is obligated to make first commercial sales and meet certain minimum sales thresholds of products or processes including, under the amended and restated agreement, a first commercial sale of a product or process no later than June 2013 and minimal sales of products thereafter ranging from $0.5 million to $5.0 million annually. M.I.T. may convert the exclusive licenses under the amended and restated license agreement to non-exclusive licenses, as its

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sole remedy, if the Company fails to meet its diligence obligations. Under the license agreement covering sequencing machines, M.I.T. has the right to treat a failure by the Company to fulfill its diligence obligations as a material breach of the license agreement.

In exchange for the licenses granted in the two agreements, the Company has paid M.I.T. license issue fees and annual license and maintenance fees ranging, in the aggregate, from $132,500 to $157,500. The Company is also required to pay M.I.T. 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 Company recorded $157,500, $157,500 and $132,500 as license and maintenance fees in the years ended December 31, 2011, 2010 and 2009, respectively, and $6.6 million and $2.0 million as royalty fees and milestone payments in the years ended December 31, 2011 and 2010, respectively, related to these agreements.

The Company granted Sandoz a sublicense under the amended and restated license 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.

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, 2011 and 2010, 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

2004 Stock Incentive Plan

The Company's 2004 Stock Incentive Plan, as amended, allows for the granting of incentive and nonstatutory stock options, restricted stock awards, stock appreciation rights and other share-based awards to employees, officers, directors, consultants and advisors. At December 31, 2011, the Company was authorized to issue up to 13,369,141 shares of common stock with annual increases (to be added on the first day of the Company's fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013) equal to the lowest of (i) 1,974,393 shares, (ii) 5% of the

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then outstanding number of common shares or (iii) such other amount as the Board of Directors may authorize. Effective January 1, 2012, the Company's Board of Directors increased the number of authorized shares by 1,974,393 shares. At December 31, 2011, the Company had 5,481,533 shares available for grant under the 2004 Stock Incentive Plan.

Incentive stock options are granted only to employees of the Company. Incentive stock options granted to employees who own more than 10% of the total combined voting power of all classes of stock 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, officers, directors, consultants and advisors. 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 has been awarded to employees, officers and directors. Some restricted stock awards vest on the achievement of corporate milestones and others awards generally vest over a four year vesting period.

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, 2011, 2010 and 2009 was $11.1 million, $10.8 million and $10.8 million, respectively.

Share-based compensation expense related to outstanding employee stock option grants was $6.2 million, $8.1 million and $7.6 million for the years ended December 31, 2011, 2010 and 2009, respectively.

In the three month period ended March 31, 2010, the Company recorded a charge to research and development expense of $0.6 million and a charge to general and administrative expense of $1.0 million, due to a correction in the application of the stock option forfeiture rates used to calculate share-based compensation during the years ending December 31, 2006, 2007 and 2008. In accordance with Securities and Exchange Commission Staff Accounting Bulletin ("SAB") No. 99, *Materiality,* and SAB No. 108, the Company assessed the materiality of these charges to its consolidated financial statements for the years ended December 31, 2006, 2007 and 2008, using both the roll-over method and iron-curtain method as defined in SAB No. 108. The Company concluded the effect of understating share-based compensation was not material to its financial statements for the years ended December 31, 2006, 2007 and 2008 and, as such, those financial statements are not materially misstated. The Company also concluded that providing for the correction of the understatement in 2010 would not have a material effect on its consolidated financial statements for the year ending December 31, 2010.

During the year ended December 31, 2011, the Company granted 955,634 stock options, of which 543,084 were in connection with annual merit awards and 412,550 were granted to new hires and members of the 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.

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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		
	2011	2010	2009	2011	2010	2009
Expected volatility	68%	71%	98%	75%	82%	95%
Expected dividends						
Expected life (years)	6.3	5.7	6.0	0.5	0.5	0.5
Risk-free interest rate	2.7%	3.0%	2.6%	0.2%	0.2%	0.6%

Under the 2004 Employee Stock Purchase Plan ("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, 2011, the Company had 230,602 shares available for grant under the ESPP. The Company issued 53,338 shares of common stock to employees under the plan during the year ended December 31, 2011. 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 that uses the assumptions 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, 2011, 2010 and 2009, the Company recorded share-based compensation expense of $0.3 million with respect to the ESPP. At December 31, 2011, subscriptions were outstanding for an estimated 21,269 shares at a fair value of approximately $5.82 per share. The weighted average grant date fair value of the offerings during 2011, 2010 and 2009 was $5.80, $5.48 and $4.88 per share, respectively.

The following table presents stock option activity of the Company's stock plan for the year ended December 31, 2011:

	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, 2011	4,260	$ 12.13		
Granted	955	14.60		
Exercised	(514)	9.69		
Forfeited	(140)	14.17		
Expired	(21)	9.65		
Outstanding at December 31, 2011	4,540	$ 12.88	6.37	$ 22,095
Exercisable at December 31, 2011	3,294	$ 12.50	5.53	$ 17,632
Vested or expected to vest at December 31, 2011	4,414	$ 12.84	6.30	$ 21,685

The weighted average grant date fair value of option awards granted during 2011, 2010 and 2009 was $9.27, $9.59 and $8.06 per option, respectively. The total intrinsic value of options exercised during 2011, 2010 and 2009 was $4.3 million, $7.5 million and $0.2 million, respectively. At December 31, 2011, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $8.7 million, including estimated forfeitures, which will be recognized over the weighted

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average remaining requisite service period of 2.3 years. The total fair value of shares vested during 2011, 2010 and 2009 was $6.4 million, $7.2 million and $7.6 million, respectively.

Cash received from option exercises for 2011, 2010 and 2009 was $5.0 million, $6.1 million and $0.2 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, 2011, the Company awarded 136,907 shares of restricted common stock to its officers in connection with its annual merit grant, which generally fully vest over the four years following the grant date. In addition, during the year ended December 31, 2011, the Company awarded 884,400 shares of performance-based restricted common stock to its employees and officers. The performance condition for these awards is the marketing approval from the FDA for M356, the Company's second major generic program, in the United States. 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 as the Company determined that it was probable the performance condition would be achieved, of $4.4 million for the year ended December 31, 2011. The Company recorded share-based compensation expense related to outstanding time-based restricted stock awards of $2.0 million for the year ended December 31, 2010. The Company recorded share-based compensation expense related to outstanding time- and performance-based restricted stock awards of $2.8 million for the year ended December 31, 2009. As of December 31, 2011, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $10.9 million, which is expected to be recognized over the weighted average remaining requisite service period of 2.3 years.

A summary of the status of nonvested shares of restricted stock as of December 31, 2011, and the changes during the year then ended, is presented below:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2011	284	$ 12.22
Granted	1,021	14.48
Vested	(147)	11.59
Cancelled	(51)	14.31
Nonvested at December 31, 2011	1,107	$ 14.29

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of December 31, 2011 are summarized below:

Vesting Schedule	Nonvested Shares (in thousands)
Time-based	267
Performance-based	840
Nonvested at December 31, 2011	1,107

The total fair value of shares of restricted stock vested during 2011, 2010 and 2009 was $1.7 million, $1.4 million and $144,000, respectively.

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12. Net Income (Loss) Per Share

The following table sets forth the Company's reconciliation of basic and diluted share amounts (amounts in thousands, except per share amounts):

	For the Years Ended December 31,		
	2011	**2010**	**2009**
Numerator:			
Net income (loss)	$ 180,356	$ 37,290	$ (64,012)
Denominator:			
Basic weighted average common shares outstanding	49,852	44,626	40,056
Weighted average common stock equivalents from assumed exercise of stock options and restricted stock awards	971	1,316	
Diluted weighted average common shares outstanding	50,823	45,942	40,056
Basic net income (loss) per common share	$ 3.62	$ 0.84	$ (1.60)
Diluted net income (loss) per common share	$ 3.55	$ 0.81	$ (1.60)
Weighted-average anti-dilutive shares related to:			
Outstanding stock options	2,062	2,187	3,935
Restricted stock awards	629	58	606

The weighted-average anti-dilutive shares shown in the foregoing table were not included in the computation of diluted net income (loss) per share. In those reporting periods in which the Company has 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 is sufficient to "buy back" the entire amount of shares. In those reporting periods in which the Company has a net loss, anti-dilutive shares comprise the impact of those 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.

13. Income Taxes

A reconciliation of the federal statutory income tax provision to the Company's actual provision for the years ended December 31, 2011, 2010 and 2009 is as follows (in thousands):

	2011	**2010**	**2009**
Provision (benefit) at federal statutory tax rate	$ 61,324	$ 12,653	$ (21,756)
State taxes, net of federal benefit	9,821	2,149	(4,014)
Change in valuation allowance	(72,364)	(15,679)	25,024
Share-based compensation	1,826	1,346	1,169
Tax credits	(643)	(488)	(485)
Other	36	19	62
Income tax provision	$	$	$

The Company generated U.S. taxable income during the years ended December 31, 2011 and 2010, and as a result, utilized $192.3 million and $26.3 million, respectively, of its available federal net operating loss carryforwards to offset this income. At December 31, 2011, the Company had federal and state net operating loss carryforwards of $25.9 million and $18.7 million, respectively, available to reduce future taxable income and which will expire at various dates through 2029. Of this amount,

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approximately $8.3 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, 2011, the Company had federal and state research and development and other credit carryforwards were $4.9 million and $3.1 million, respectively, available to reduce future tax liabilities and which will expire at various dates beginning in 2017 through 2030.

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, 2011 and 2010 are as follows (in thousands):

	December 31,	
	2011	2010
Deferred tax assets:		
Federal and state net operating losses	$ 6,561	$ 83,013
Research credits	6,987	5,935
Deferred compensation	8,159	7,314
Deferred revenue	1,478	2,323
Accrued expenses	1,327	246
Intangibles	2,429	325
Capital leases		781
Unrealized loss on marketable securities	28	6
Total deferred tax assets	26,969	99,943
Deferred tax liabilities:		
Depreciation	(15)	(1,046)
Total deferred tax liabilities	(15)	(1,046)
Valuation allowance	(26,954)	(98,897)
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 decreased by $71.9 million for the year ended December 31, 2011, primarily as a result of the current period net income.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for the years ended December 31, 2011 and 2010 (in thousands), is as follows:

	2011	2010
Balance, beginning of year	$ 2,396	$ 4,066
Additions for tax positions related to the current year	429	337
Reductions of tax positions of prior years		(2,007)
Balance, end of year	$ 2,825	$ 2,396

As of December 31, 2011, the Company had $2.8 million of gross unrecognized tax benefits, $2.7 million of which, if recognized, would impact the Company's effective tax rate. As of December 31, 2010, the Company had $2.4 million of gross unrecognized tax benefits, $2.3 million of which, if recognized, would impact the Company's effective tax rate. The difference between the total amount of the unrecognized tax benefits and the amount that would affect the effective tax rate consists of the federal tax benefit of state research and development credits.

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The Company reassessed its reserve relating to losses of tax benefits from an ownership change under Internal Revenue Code Section 382 in 2010. As a result of that reassessment and recalculation, the related reserve for unrecognized benefits was reduced by $2.0 million as shown in the above table.

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 since the adoption of ASC 740-10.

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 multiple state jurisdictions. The Company is no longer subject to any tax assessment from an income tax examination for years before 2004, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2004. Currently the Company is not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

During 2010, the Company applied for and received approval for all four of its applications for the Qualifying Therapeutic Discovery Project under Internal Revenue Code Section 48D and received a tax grant of approximately $1.0 million which is included in other income (expense) in the consolidated statement of operations. The tax grant reduced the Company's federal and state net operating loss carryforwards by approximately $1.0 million and reduced its 2009 federal research and development credit carryforwards by approximately $21,000.

14. Commitments and Contingencies

Capital and Operating Leases

In December 2005, the Company entered into a Master Lease Agreement (the "Agreement") with General Electric Capital Corporation ("GECC"). Under the Agreement, the Company may lease office, laboratory, computer and other equipment from GECC by executing specified equipment schedules with GECC. Each equipment schedule specifies the lease term with respect to the underlying leased equipment. As of December 31, 2008, the Company had drawn $9.6 million against the Agreement and no additional amounts were drawn in the years ending December 31, 2009, December 31, 2010 and December 31, 2011. Borrowings under the Agreement are payable over a 54-month period at effective annual interest rates of 7.51% to 9.39%. In accordance with the Agreement, should the effective corporate income tax rate for calendar-year taxpayers increase above 35%, GECC will have the right to increase rent payments by requiring payment of a single additional sum, calculated in accordance with the Agreement. The Agreement also provides the Company an early purchase option after 48 months at a predetermined fair market value, which the Company intended to exercise. As a result, the Agreement is considered a capital lease for accounting purposes and the equipment is included in property and equipment. Under the Agreement, if any material adverse change in the Company or its business occurs, as solely determined by GECC, the total unpaid principal would become immediately due and payable. There have been no events of default under this agreement. The Company repaid all borrowings during 2011.

The Company leases office space and equipment under various operating lease agreements. Rent expense for office space under operating leases amounted to $6.9 million, $5.2 million and $5.4 million for the years ended December 31, 2011, 2010 and 2009, respectively.

In September 2004, the Company entered into the West Kendall Sublease for 53,323 square feet of office and laboratory space for a term of 80 months. In November 2005, the Company amended the West Kendall Sublease to lease an additional 25,131 square feet through April 2011. Under the lease amendment, the landlord agreed to finance the leasehold improvements. The Company commenced expensing the applicable rent on a straight-line basis beginning with the commencement of the

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construction period. As the Company was the owner of the leasehold assets during the construction period it recorded $3.2 million in leasehold improvements offset by a $3.2 million lease financing liability. The construction period was completed in June 2006. As of December 31, 2011, the Company had fully amortized the lease financial liability. On April 22, 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 at 320 Bent Street, Cambridge, Massachusetts, for a term of approximately 18 months (the "320 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 320 Bent Sublease are approximately $2.3 million.

As the Company repaid all borrowings under its Agreement with GECC during 2011, there are no future minimum capital lease commitments as of December 31, 2011. Total operating lease commitments as of December 31, 2011 are as follows (in thousands):

		Operating Lease
2012	$	6,995
2013		6,062
2014		4,750
2015		1,612
2016 and beyond		
Total future minimum lease payments	$	19,419

License Agreements

In connection with license arrangements with the research university discussed in Note 9, the Company has certain annual fixed obligations to pay fees for the technology licensed. Beginning in 2010, the annual financial obligations, which extend through the life of the patent and are approximately $0.2 million per year. The Company may terminate the agreements 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.

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Legal Contingencies

In August 2008, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against the Company, Sandoz and Novartis AG in the United Stated 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 alleges infringement by the Company, Sandoz and Novartis AG of Orange Book patents owned by Yeda and licensed by Teva and seeks monetary, injunctive and declaratory relief. In November 2008, the Company and Sandoz each filed responsive pleadings denying the allegations of infringement, setting forth affirmative defenses based on invalidity, non-infringement and inequitable conduct and counterclaims seeking declaratory relief that the patent rights of Teva and Yeda pertaining to M356 are either not infringed, invalid or unenforceable. 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 us and Sandoz. In April 2011, Teva filed a motion for summary judgment of no inequitable conduct. In June 2011, the court denied Teva's motion and granted a bench trial, which occurred in July 2011, to hear the issue of inequitable conduct only. The trial on the remaining issues occurred in September 2011 in the consolidated case. There is no defined timeframe for the court to issue a decision.

In December 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and the Company for patent infringement related to certain non-Orange Book patents after Teva's motion to add those patents to the ongoing Paragraph IV litigation was denied. In January 2010, the Company and Sandoz filed a motion to dismiss this second suit on several grounds, including the failure of Teva to state an actionable legal claim and lack of subject matter jurisdiction. The motion is pending.

While the Company has vigorously defended these suits, a delay in a final judgment could significantly delay, impair or prevent its ability to commercialize M356 and the Company's business could be materially harmed. Litigation involves many risks and uncertainties, and there is no assurance that Novartis AG, Sandoz or the Company will prevail in either lawsuit. At this time, the Company believes a loss is not probable.

In September 2011, the Company sued Amphastar Pharmaceuticals Inc. ("Amphastar"), Watson Pharmaceuticals Inc. ("Watson"), 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, Watson and International Medical Systems, Ltd. from selling their enoxaparin sodium 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, Watson 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 the Company and Sandoz to post a security bond of $100 million to maintain the preliminary injunction. Amphastar, Watson and International Medical Systems, Ltd. filed a notice to appeal the decision and an emergency motion to dissolve or stay the preliminary injunction. In January 2012, the Court of Appeals for the Federal Circuit granted the motion to stay the preliminary injunction, pending appeal. The collateral for the security bond posted in the litigation remains outstanding. In the event that the Company loses the case at the District Court, it is determined that the preliminary injunction was improvidently granted, and Amphastar and Watson are able to prove they suffered damages as a result of the injunction during the period the preliminary injunction was in effect, the Company could be liable for damages for up to $35 million of the security bond.

While the Company intends to vigorously prosecute this action against Watson and Amphastar, and believes that it can ultimately prove its case in court, this suit could last a number of years. As a result,

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absent preliminary injunctive relief, recovery of lost profits and damages could await a final judgment after an appeal of a district court decision. Litigation involves many risks and uncertainties, and there is no assurance that the Company or Sandoz will prevail in these patent enforcement suits.

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 $0.5 million, $0.5 million and $0.4 million of such match expense in the years ended December 31, 2011, 2010 and 2009, respectively.

16. Related Party Transactions

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 is 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 sheet as of December 31, 2011. The developed technology is being amortized over the estimated useful life of the enoxaparin sodium injection developed technology of approximately 10 years.

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17. Asset Purchase

On December 5, 2011, the Company entered into an asset purchase agreement, or the Virdante Purchase Agreement, with Virdante Pharmaceuticals, Inc., or Virdante, a developer of sialic switch technology. Pursuant to the Virdante Purchase Agreement, the Company acquired the sialic switch assets of Virdante, including intellectual property and cell lines, relating to the sialylation of intravenous immunoglobulin and other proteins. In exchange, the Company agreed to make an upfront payment of $4.5 million which was charged as in-process research and development expense and is included in research and development expense in the consolidated statement of operations for the year ended December 31, 2011. The Company may make additional contingent milestone payments, which, if all development and regulatory milestones are achieved, will total $51.5 million.

18. Subsequent Events

The Company evaluated events and transactions after the date of the balance sheet date but prior to the issuance of the financial statements for potential recognition or disclosure in its financial statements. The Company did not identify any material subsequent events requiring adjustment (recognized subsequent events). Other than the Baxter collaboration discussed below, the Company did not identify any material subsequent events requiring disclosure.

On December 22, 2011, the Company and Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, "Baxter") entered into a Development, License and Option Agreement (the "Baxter Agreement") under which the Company agreed to collaborate, on a world-wide basis, on the development and commercialization of two follow-on biologic products. In addition, Baxter has the right to select up to four additional follow-on biologic products to be included in the collaboration. The Baxter Agreement became effective on February 13, 2012, following expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended.

Under the terms of the Baxter Agreement, Baxter agreed to pay the Company:

- an upfront payment of $33 million;
- technical and development milestone payments totaling up to $91 million across the six product candidates;
- regulatory milestones totaling up to $300 million, on a sliding scale, across the six 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;
- option payments totaling $28 million for the exercise of the options with respect to the additional four product candidates that can be named under the Baxter Agreement, and payments of $5 million each for extensions of the period during which such additional products may be named; and
- 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.

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

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arrangement, the Company will generally be responsible for research and process development costs prior to filing an Investigational New Drug Application and the cost of in-human clinical trials, manufacturing in accordance with current good manufacturing practices and commercialization will be borne by Baxter.

Under the Baxter Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all therapeutic indications. In addition, the Company has agreed, for a period commencing six months following the effective date and ending on the earlier of three years from the effective date of the Baxter Agreement (subject to certain limited time extensions as provided for in the Baxter Agreement) or the selection of the four additional products, to notify Baxter of bona fide offers from third parties to develop or commercialize a follow-on biologic product 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 Investigational New Drug 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 follow-on biologic products not named under the Baxter Agreement, subject to certain restrictions.

The collaboration is governed by 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.

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;
- by 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;
- by Baxter for its convenience; or
- by 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.

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19. Selected Quarterly Financial Data (Unaudited)

	Quarter Ended			
(in thousands, except per share data)	**March 31**	**June 30**	**September 30**	**December 31**
2011				
Product revenue	$ 75,761	$ 83,848	$ 84,717	$ 26,148
Research and development revenue	$ 2,411	$ 3,648	$ 3,228	$ 3,307
Total collaboration revenue	$ 78,172	$ 87,496	$ 87,945	$ 29,455
Net income (loss)	$ 57,006	$ 64,265	$ 60,338	$ (1,253)
Basic net income (loss) per common share	$ 1.15	$ 1.29	$ 1.21	$ (0.02)
Diluted net income (loss) per common share	$ 1.13	$ 1.26	$ 1.18	$ (0.02)
Shares used in computing basic net income (loss) per common share	49,532	49,708	50,034	50,128
Shares used in computing diluted net income (loss) per common share	50,334	51,001	51,048	50,128
2010				
Product revenue	$	$	$ 44,188	$ 52,437
Research and development revenue	$ 3,690	$ 2,795	$ 7,773	$ 5,889
Total collaboration revenue	$ 3,690	$ 2,795	$ 51,961	$ 58,326
Net income (loss)	$ (16,084)	$ (15,004)	$ 32,120	$ 36,258
Basic net income (loss) per common share	$ (0.37)	$ (0.34)	$ 0.72	$ 0.79
Diluted net income (loss) per common share	$ (0.37)	$ (0.34)	$ 0.70	$ 0.77
Shares used in computing basic net income (loss) per common share	43,752	44,069	44,719	45,940
Shares used in computing diluted net income (loss) per common share	43,752	44,069	46,032	46,930

Net income (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.

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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, 2011. The term "disclosure controls and procedures," as defined in Rules 13a-15I and 15d-15I 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, 2011, 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

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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, 2011. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control Integrated Framework."

Based on its assessment, our management has concluded that, as of December 31, 2011, our internal control over financial reporting is effective based on those criteria.

The independent registered public accounting firm that audited our financial statement 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, 2011, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (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

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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, 2011, 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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2011 of Momenta Pharmaceuticals, Inc. and our report dated February 28, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 28, 2012

(c) Changes in Internal Control Over Financial Reporting

None

Item 9B. OTHER INFORMATION

Not applicable.

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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 2012 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 2012 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 2012 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 2012 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 2012 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 2012 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

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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.

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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 this 28th day of February, 2012.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ CRAIG A. WHEELER

Craig A. Wheeler
Chief Executive Officer

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

Signature	Title	Date
/s/ CRAIG A. WHEELER Craig A. Wheeler	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2012
/s/ RICHARD P. SHEA Richard P. Shea	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2012
/s/ JAMES SULAT James Sulat	Chairman of the Board and Director	February 28, 2012
/s/ JOHN K. CLARKE John K. Clarke	Director	February 28, 2012
/s/ MARSHA H. FANUCCI Marsha H. Fanucci	Director	February 28, 2012
/s/ PETER BARTON HUTT Peter Barton Hutt	Director	February 28, 2012
Bruce Downey	Director	
/s/ THOMAS KOESTLER Thomas Koestler	Director	February 28, 2012
/s/ BENNETT M. SHAPIRO Bennett M. Shapiro	Director	February 28, 2012

/s/ ELIZABETH STONER Elizabeth Stoner	Director	February 28, 2012

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EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference to Filing			
		Form or Schedule	Exhibit No.	Date with SEC	SEC File Number
	Articles of Incorporation and By-Laws				
3.1	Third Amended and Restated Certificate of Incorporation	S-1	3.3	3/11/2004	333-113522
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

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Exhibit Number	Description	Incorporated by Reference to Filing			
		Form or Schedule	Exhibit No.	Date with SEC	SEC File Number
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
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	Exclusive Patent License Agreement, dated October 31, 2002, by and between the Massachusetts Institute of Technology and the Registrant (the "October 31, 2002 M.I.T. License"); First Amendment to the October 31, 2002 M.I.T. License, dated November 15, 2002, by and between the Massachusetts Institute of Technology and the Registrant	S-1/A	10.6	5/11/2004	333-113522
10.6	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
10.7	Second Amendment to the October 31, 2002 M.I.T. License, dated July 17, 2004, by and between the Massachusetts Institute of Technology and the Registrant	10-Q	10.4	8/16/2004	000-50797
10.8	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
10.9	Third Amendment to the October 31, 2002 M.I.T. License, dated August 5, 2006, by and between the Massachusetts Institute of Technology and the Registrant	10-Q	10.4	11/8/2006	000-50797
10.10	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
10.11	Fourth Amendment to the October 31, 2002 M.I.T. License, dated January 10, 2007, by and between the Massachusetts Institute of Technology and the Registrant	10-K	10.11	3/15/2007	000-50797
10.12	Letter Agreement dated January 29, 2007 between Sandoz AG and the Registrant	10-K	10.16	3/15/2007	000-50797
10.13	Letter Agreement dated February 1, 2007 between Sandoz AG and the Registrant	10-Q	10.2	5/10/2007	000-50797

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Exhibit Number	Description	Incorporated by Reference to Filing			
		Form or Schedule	Exhibit No.	Date with SEC	SEC File Number
10.14	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
10.15	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
10.16	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
10.17	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
10.18	Amendment No. 2, dated December 11, 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
10.19	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
*10.20	Letter Agreement dated November 8, 2011 by and between the Registrant, Sandoz AG and Sandoz Inc.				
*10.21	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				
10.22	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				
10.23#	Amended and Restated 2002 Stock Incentive Plan	10-K	10.17	3/15/2007	000-50797
10.24#	2004 Stock Incentive Plan, as amended	10-K	10.18	3/15/2007	000-50797
10.25#	Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.1	8/16/2004	000-50797
10.26#	Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.2	8/16/2004	000-50797

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Exhibit Number	Description	Incorporated by Reference to Filing			
		Form or Schedule	Exhibit No.	Date with SEC	SEC File Number
10.27#	Form of Restricted Stock Agreement Under 2004 Stock Incentive Plan	8-K	10.2	2/28/08	000-50797
10.28#	2004 Employee Stock Purchase Plan	10-Q	10.1	5/6/2010	000-50797
10.29#	Non-Employee Director Compensation Summary	10-Q	10.3	8/5/2011	000-50797
10.30#	Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.31#	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	
10.32#	Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.8	11/8/2006	000-50797
10.33#	Nonstatutory Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.9	11/8/2006	000-50797
10.34#	Incentive Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.10	11/8/2006	000-50797
10.35#	Restricted Stock Agreement, dated December 15, 2006, between John E. Bishop and the Registrant	10-K	10.56	3/15/2007	000-50797
10.36#	Restricted Stock Agreement, dated December 14, 2007, between John E. Bishop and the Registrant	10-K	10.35	3/10/2008	000-50797
10.37#	Restricted Stock Agreement, dated August 15, 2007, between Richard P. Shea and the Registrant	10-Q	10.1	11/08/2007	000-50797
10.38#	Restricted Stock Agreement, dated January 17, 2007, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.39#	Form of Employment Agreement for executive officers	10-Q	10.3	5/9/2008	000-50797
10.40#	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
10.41#	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
10.42#	Form of Amendment to the Employment Agreement for executive officers dated December 15, 2010	10-K	10.39	3/11/3011	

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Exhibit Number	Description	Incorporated by Reference to Filing			
		Form or Schedule	Exhibit No.	Date with SEC	SEC File Number
10.43#	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
10.44	Form of Restricted Stock Agreement	8-K	10.1	4/1/2011	000-50797
	Material Contracts Leases				
10.45	Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.9	11/12/2004	000-50797
10.46	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
10.47	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
10.48	Third Amendment to Sublease (regarding Sublease Agreement, dated September 14, 2004, as amended), effective as of January 27, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant	10-K	10.48	3/16/2006	000-50797
10.49	Letter Agreement (regarding Sublease Agreement, dated September 14, 2004, as amended), dated June 29, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.01	8/9/2006	000-50797
	Material Contracts Stock Purchase Agreement				
10.50	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				
10.51	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
10.52	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

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Exhibit Number	Description	Incorporated by Reference to Filing			
		Form or Schedule	Exhibit No.	Date with SEC	SEC File Number
10.53	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
*10.54	Asset Purchase Agreement dated December 5, 2011 between the Registrant and Virdante Pharmaceuticals, Inc.				
	Additional Exhibits				
*21	List of Subsidiaries				
*23.1	Consent of Independent Registered Public Accounting Firm				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				
101.INS	XBRL Instance Document.**				
101.SCH	XBRL Taxonomy Extension Schema Document.**				
101.CAL	XBRL Taxonomy Calculation Linkbase Document.**				
101.LAB	XBRL Taxonomy Label Linkbase Document.**				
101.PRE	XBRL Taxonomy Presentation Linkbase Document.**				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document. **				
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

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The following financial information from Momenta Pharmaceuticals, Inc.'s Annual Report on Form 10-K for the period ended December 31, 2011, filed with the SEC on February 28, 2012, formatted in Extensible Business Reporting Language (XBRL): (i) the Consolidated Statements of Operations for the years ended December 31, 2011, 2010 and 2009, (ii) the Consolidated Balance Sheets as of December 31, 2011 and 2010, (iii) the Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009, (iv) the Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for the years ended December 31, 2011, 2010 and 2009 and (v) Notes to Consolidated Financial Statements.

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Annual Report on Form 10-K is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.