

MOMENTA PHARMACEUTICALS INC

FORM 10-K (Annual Report)

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

Or

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

For the transition period from _____ to _____

Commission file number: 000-50797

MOMENTA PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

04-3561634

(I.R.S. Employer Identification No.)

675 West Kendall Street, Cambridge, Massachusetts 02142

(Address of principal executive offices) (zip code)

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

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

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

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be

contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a smaller reporting company)

Smaller reporting company

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

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on June 30, 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 biologics. 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

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

Program		Discovery	Development	Market
Complex Generics	Enoxaparin (Polysaccharide)	[Progress bar spanning Discovery, Development, and Market]		
	M356 (Peptide)	[Progress bar spanning Discovery and Development]		
Follow-on Biologics	M923 (Protein)	[Progress bar in Discovery]		
	M834 (Protein)	[Progress bar in Discovery]		
Novel Therapeutics	M402 (Polysaccharide)	[Progress bar in Discovery]		
	Adomiparin (Polysaccharide)	[Progress bar spanning Discovery and Development]		
	Research Candidates	[Progress bar in Discovery]		

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

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

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.

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.

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.

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.

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.

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%.

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

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.

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, exemption, 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

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

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

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

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

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.

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

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

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.

The new Section 351(k) pathway further defines a subset of biosimilar products as "interchangeable" if an applicant can demonstrate that:

- the interchangeable biological product can be expected to produce the same clinical result as the brand biologic product in any given patient; and
- if the product is administered more than once in a patient, that the risk in terms of safety or diminished efficacy of alternating or switching between the use of the interchangeable biologic product and the brand biologic product is no greater than the risk of using the brand biologic product without switching.

The new Section 351(k) pathway states that a biosimilar product that is determined to be interchangeable may be substituted for the brand biologic product without the intervention of a health care provider who prescribed the brand biologic product. The law states that the biosimilar must be for the same indication as the brand biologic, involve the same mechanism of action and that the manufacturing facility meets the standards necessary to assure that the product continues to be safe, pure and potent. The types of data that would ordinarily be required in an application to show similarity would include:

- analytical data and studies to demonstrate chemical similarity;
- 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.

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

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

under a BLA before accepting a filing for a biosimilar version of the brand product, and the FDA cannot approve a biosimilar version of the brand product until 12 years after the brand product was approved under a BLA. In addition, the new legislation redefines the definition of biologic versus drug and, as a result, a number of products that were previously regulated as drugs may now be regulated as biologics. There is a ten year transition period during which applicants can elect regulation as a drug or as a biologic when applications are filed. For example, heparin based products may now have the option of filing for approval as a biologic. This could provide an applicant that elects regulation as a biologic with the longer twelve year period of exclusivity protection as compared to the five year period of exclusivity protection against generic drug competition.

Post-Approval Requirements

After regulatory approval of a product is obtained, we will be required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, BLA, ANDA or Section 351(k) application, the FDA may require post-marketing testing and surveillance to further assess and monitor the product's safety or efficacy after commercialization. Any post-approval regulatory obligations, and the cost of complying with such obligations, could expand in the future.

In addition, holders of an approved NDA, BLA, ANDA or Section 351(k) approval are required to report, among other things, certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Discovery of problems with a product or failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an IRB of a clinical hold on or termination of studies, the FDA's refusal to approve pending applications or supplements, license suspension or revocation, withdrawal of an approval, restriction on marketing, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products if and when we enter those markets. Whether or not we obtain FDA approval for a product, we must obtain approval of a clinical trial application or product from the applicable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure is mandatory for the approval of biotechnology products and many pharmaceutical products and provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized

procedure provides for mutual recognition of national approval decisions and is available at the request of the applicant for products that are not subject to the centralized procedure. Under this procedure, the holder of a national marketing authorization from one European Union member state (the reference member state) may submit an application to the remaining member states. Generally, each member state decides whether to recognize the reference member state's approval in its own country.

Related Matters

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA or reimbursed under Medicare by the Center for Medicare Services. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations 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

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. Xarelto® 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 Synthron BV & Synthron 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

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.

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

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

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

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.

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

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.

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.

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

executive officers would result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and approval of our product candidates. In addition, there is intense competition from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, for human resources, including management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful development and commercialization of our product candidates.

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

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

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

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

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

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

- we may find that the acquired company or assets does not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;
- difficulty integrating the operations and personnel of the acquired business, and difficulty retaining the key personnel of the acquired business;
- difficulty incorporating the acquired technologies;
- difficulties or failures with the performance of the acquired technologies or drug products;
- we may face product liability risks associated with the sale of the acquired company's products;
- disruption or diversion of management's attention by transition or integration issues and the complexity of managing diverse locations;
- difficulty maintaining uniform standards, internal controls, procedures and policies;
- the acquisition may result in litigation from terminated employees or third parties; and
- we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

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

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

Risks Relating to Development and Regulatory Approval

If we are not able to obtain regulatory approval for commercial sale of our generic product candidate, M356, as a therapeutic equivalent to Copaxone, our future results of operations will be adversely affected.

Our future results of operations depend to a significant degree on our ability to obtain regulatory approval for and commercialize M356. We will be required to demonstrate to the satisfaction of the FDA, among other things, that M356:

- contains the same active ingredients as Copaxone;
- is of the same dosage form, strength and route of administration as Copaxone, and has the same labeling as the approved labeling for Copaxone, with certain exceptions; and

- meets compendial or other applicable standards for strength, quality, purity and identity, including potency.

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

Determination of therapeutic equivalence of M356 to Copaxone will be based, in part, on our demonstration of the chemical equivalence of our versions to their respective reference listed drugs. The FDA may not agree that we have adequately characterized M356 or that M356 and Copaxone are chemical equivalents. In that case, the FDA may require additional information, including 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

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

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.

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;

- 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

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

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.

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 partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

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

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.

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.

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

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.

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

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;

- 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.

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:

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

* 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 States Federal District Court in the Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for M356. The suit 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

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.

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:

<u>Quarter ended</u>	<u>High</u>	<u>Low</u>
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

Holdings

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

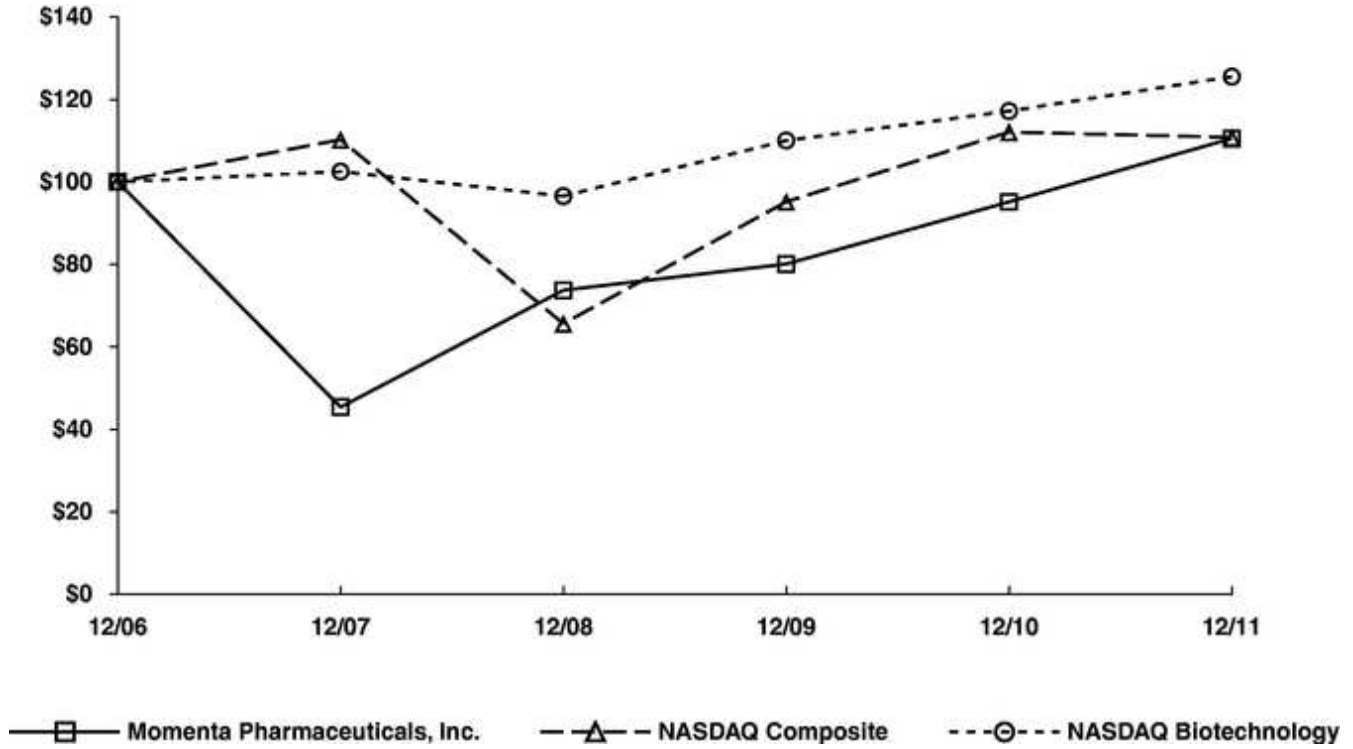
Information relating to compensation plans under which our equity securities are authorized for issuance is set forth in Item 12 below.

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.

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

	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

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

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.

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

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	<u>270,473</u>	<u>96,625</u>	<u>—</u>
Research and development revenue:			
Regulatory milestone revenue	—	5,000	—
Research and development revenue	12,595	15,147	20,249
Total research and development revenue	<u>12,595</u>	<u>20,147</u>	<u>20,249</u>
Total collaboration revenue	<u>\$ 283,068</u>	<u>\$ 116,772</u>	<u>\$ 20,249</u>

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.

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.

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.

Commercial and Development Programs (Status)	Research and Development Expense (in thousands)			Project Inception to December 31, 2011
	2011	2010	2009	
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 Viridante 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

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.

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 Viridante of \$4.5 million, depreciation and amortization of our property, equipment and intangible assets of \$5.5 million, amortization of purchased premiums on our marketable securities of \$1.7 million, and losses on disposals of fixed assets of \$0.2 million. In addition, the net change in our operating assets and liabilities provided cash of

\$10.3 million and resulted from: a decrease in accounts receivable of \$26.3 million, due to a decrease in 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.

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	<u>\$ 21,632</u>	<u>\$ 7,478</u>	<u>\$ 11,727</u>	<u>\$ 2,427</u>	<u>\$ —</u>

* 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.

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.

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,

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

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

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.

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

Momenta Pharmaceuticals, Inc.

Consolidated Balance Sheets

(In thousands, except per share amounts)

	<u>December 31,</u>	
	<u>2011</u>	<u>2010</u>
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	<u>399,421</u>	<u>214,302</u>
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	<u>\$ 420,909</u>	<u>\$ 227,569</u>
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	<u>16,028</u>	<u>17,652</u>
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	<u>17,831</u>	<u>21,466</u>
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	<u>403,078</u>	<u>206,103</u>
Total liabilities and stockholders' equity	<u>\$ 420,909</u>	<u>\$ 227,569</u>

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

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	<u>283,068</u>	<u>116,772</u>	<u>20,249</u>
Operating expenses:			
Research and development*	64,657	51,712	60,612
General and administrative*	38,710	28,595	23,800
Total operating expenses	<u>103,367</u>	<u>80,307</u>	<u>84,412</u>
Operating income (loss)	<u>179,701</u>	<u>36,465</u>	<u>(64,163)</u>
Other income (expense):			
Interest income	746	176	825
Interest expense	(91)	(329)	(570)
Other income (expense)	—	978	(104)
Total other income	<u>655</u>	<u>825</u>	<u>151</u>
Net income (loss)	<u>\$ 180,356</u>	<u>\$ 37,290</u>	<u>\$ (64,012)</u>
Net income (loss) per share:			
Basic	<u>\$ 3.62</u>	<u>\$ 0.84</u>	<u>\$ (1.60)</u>
Diluted	<u>\$ 3.55</u>	<u>\$ 0.81</u>	<u>\$ (1.60)</u>
Weighted average shares outstanding:			
Basic	<u>49,852</u>	<u>44,626</u>	<u>40,056</u>
Diluted	<u>50,823</u>	<u>45,942</u>	<u>40,056</u>
* 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.

Momenta Pharmaceuticals, Inc.

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

(In thousands)

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>		<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Par</u>	<u>Paid-In</u>	<u>Other</u>		<u>Deficit</u>	<u>Stockholders'</u>
		<u>Value</u>	<u>Capital</u>	<u>Income</u>			<u>Equity</u>
				<u>(Loss)</u>			
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	<u>51,285</u>	<u>\$ 5</u>	<u>\$ 506,557</u>	<u>\$ (81)</u>	<u>\$ (103,403)</u>	<u>\$ 403,078</u>

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

Momenta Pharmaceuticals, Inc.
Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	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	<u>213,725</u>	<u>(1,057)</u>	<u>(55,294)</u>
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	<u>(268,720)</u>	<u>19,065</u>	<u>(22,273)</u>
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	<u>3,559</u>	<u>60,739</u>	<u>44,431</u>
(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	<u>\$ 49,245</u>	<u>\$ 100,681</u>	<u>\$ 21,934</u>
Supplemental Cash Flow Information:			
Cash paid for interest	<u>\$ 91</u>	<u>\$ 329</u>	<u>\$ 570</u>
Supplemental Non-Cash Information:			
Issuance of common stock for payment of Parivid milestone	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,000</u>

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

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

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

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

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

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.

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):

	<u>For the Years Ended December 31,</u>		
	<u>2011</u>	<u>2010</u>	<u>2009</u>
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)	<u>\$ 180,291</u>	<u>\$ 37,281</u>	<u>\$ (64,433)</u>

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.

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.



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):

<u>As of December 31, 2011</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
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

<u>As of December 31, 2010</u>	<u>Amortized Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
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

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,		Depreciable Lives
	2011	2010	
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)	
	<u>\$ 13,327</u>	<u>\$ 9,003</u>	

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.

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		December 31, 2010	
		Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	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
	<u>\$ 9,131</u>	<u>\$ 9,098</u>

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

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

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

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

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.

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

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	<u>1,107</u>	<u>\$ 14.29</u>

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	<u>1,107</u>

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.

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,

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	<u>26,969</u>	<u>99,943</u>
Deferred tax liabilities:		
Depreciation	(15)	(1,046)
Total deferred tax liabilities	<u>(15)</u>	<u>(1,046)</u>
Valuation allowance	(26,954)	(98,897)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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	<u>\$ 2,825</u>	<u>\$ 2,396</u>

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.

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

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):

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

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.

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 States Federal District Court in the Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for M356. The suit 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,

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.

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

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.

19. Selected Quarterly Financial Data (Unaudited)

<u>(in thousands, except per share data)</u>	<u>Quarter Ended</u>			
	<u>March 31</u>	<u>June 30</u>	<u>September 30</u>	<u>December 31</u>
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.

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

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

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.

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.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are included as part of this Annual Report on Form 10-K.

1. Financial Statements:

	<u>Page number in this report</u>
Report of Independent Registered Public Accounting Firm	73
Consolidated Balance Sheets at December 31, 2011 and 2010	74
Consolidated Statements of Operations for the years ended December 31, 2011, 2010 and 2009	75
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for the years ended December 31, 2011, 2010 and 2009	76
Consolidated Statements of Cash Flows for the years ended December 31, 2011, 2010 and 2009	77
Notes to Consolidated Financial Statements	78

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.

EXHIBIT INDEX

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
<i>Articles of Incorporation and By-Laws</i>					
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
<i>Instruments Defining the Rights of Security Holders</i>					
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
<i>Material Contracts—License Agreements</i>					
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

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing 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

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing 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
	<i>Material Contracts—Management Contracts and Compensation Plans</i>				
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

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing 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	

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing 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
<i>Material Contracts—Leases</i>					
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
<i>Material Contracts—Stock Purchase Agreement</i>					
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
<i>Material Contracts—Asset Purchase Agreement</i>					
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

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing 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.				
	<i>Additional Exhibits</i>				
*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

Table of Contents

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.



November 8, 2011

Jeff George
Sandoz AG
Lichtstrasse 35
CH-4058 Basel
Switzerland

Don DeGolyer
Sandoz Inc.
506 Carnegie Center, Suite 400
Princeton, New Jersey 08540

Re: Allocation of Preliminary Injunction Bond Liability under the Joint Prosecution/Common Interest Agreement

Dear Jeff and Don:

Reference is hereby made to the Collaboration and License Agreement (the "Agreement") entered into as of November 1, 2003 by and among Sandoz AG (via assignment from Sandoz N.V. (f/k/a Biochemie West Indies N.V.)), Sandoz Inc. (f/k/a Geneva Pharmaceuticals, Inc.) (collectively, "Sandoz") and Momenta Pharmaceuticals, Inc. ("Momenta") (Sandoz or Momenta, a "Party", and together, the "Parties"). Reference is also made to the letter agreement attached hereto (the "Amphastar Litigation Letter") dated September 22, 2011 among the Parties relating to the mechanics, lead role, allocation of costs, and allocation of damages or settlements pursuant to Section 8.7 of the Agreement in relation to the patent infringement suit filed by Momenta and Sandoz against Amphastar Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc. and/or their appropriate subsidiaries, affiliates, agents and distributors (the "Amphastar Litigation") as well as the letter referenced therein dated December 1, 2010 and executed by the Parties in connection with the initiation of litigation against Teva Pharmaceuticals (the "Section 8.7 Implementation Letter") (such suit against Teva referred to herein as the "Teva Litigation"). Capitalized terms used in this letter that are not otherwise defined in this letter shall have the meanings ascribed to them in the Agreement.

The Parties hereby agree that paragraphs 5 and 6 of the Section 8.7 Implementation Letter are amended and restated as follows:

5. The JSC expressly reserves the right to approve in writing, or to delegate to an officer of each Party, the right to approve in writing, the posting of a bond or bonds in connection with the issuance of a preliminary injunction in the Amphastar Litigation and in the Teva Litigation. With respect to the Amphastar Litigation, the Parties agree as follows:

- a. For the period prior to March 1, 2012, Momenta shall post a bond of \$35 million and Sandoz shall post of bond of \$65 million on or before the close of business on November 10, 2011 to satisfy the \$100 million bond requirement established by the court to maintain the preliminary injunction against Amphastar Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc. and/or their appropriate subsidiaries, affiliates, agents and distributors (the "Defendants"). Each Party shall bear its own costs for such bonds. The Parties agree that should the Aventis TPC Period (as further discussed in paragraph b, below) terminate prior to March 1, 2012, each Party shall bear ultimate liability for payment of damages to the Defendants as a result of the injunctive relief awarded (should such damages be awarded by the court) in the following allocated percentages: sixty-five percent (65%) by Sandoz and thirty-five percent (35%) by Momenta; provided that such damages so awarded to Defendants are not in excess of the current \$100 million aggregate bond obligation.
- b. If as of the close of business on February 29, 2012, the Aventis TPC Period remains in effect under Section 4.8 of the Agreement (which provides for payment of a hybrid royalty and profit share arrangement), then:
 - i. Momenta shall, to the extent the preliminary injunction and bonding obligation remain in effect, post an additional bond in the amount of \$15 million and Sandoz shall have the right to reduce its bond obligation by such amount. The Parties shall cooperate to ensure the replacement of bonding responsibility occurs in a timely manner on March 1, 2012 and without disruption to the preliminary injunction.
 - ii. Subject to paragraph c., Momenta and Sandoz shall each thereafter be liable for fifty percent (50%) of the liability for payment of damages to the Defendants as a result of the injunctive relief awarded should such damages be awarded by the Court.
- c. Should the court determine that the bond requirements are insufficient, the Parties shall discuss and consider an increase in good faith, but

neither Party shall be obligated to post a bond in excess of the applicable obligations set forth in paragraphs a and b, above, or to otherwise assume liability to the other Party for damages to the Defendants as a result of the injunctive relief awarded should such damages be awarded by the Court in excess of the limits set forth in paragraphs a and b, above. Each Party may elect to proceed at its sole risk and expense to post an increase in any such bond requirements in support of a preliminary injunction, and such Party shall bear all responsibility for damages, interest, penalties, attorney's fees or other expenses in excess of the applicable obligated liability amounts of the other Party under paragraphs a and b, above in connection with the continuation of the preliminary injunction or the bond after such Party makes such election to post an increase in the bond and continue the preliminary injunction. Notwithstanding anything contained in the Amphastar Litigation Letter, the Section 8.7 Litigation Letter, or herein, the Parties expressly agree that neither Party shall have the right to withdraw its agreed-upon share of the bond or disclaim its agreed-upon allocated liability for damages related to the Amphastar Litigation without the prior, written consent of the other Party.

6. In the event of the approval by both Parties to post security in support of a temporary restraining order and a preliminary injunction in the Teva Litigation, Momenta and Sandoz shall each be liable for (a) posting fifty percent (50%) of the bonding requirement at their own expense and (b) fifty (50%) of the liability for payment of damages to the defendants in the Teva Litigation as a result of any such injunctive relief awarded should such damages be awarded by the Court. If the Parties do not otherwise agree to post a bond, then either Party, may elect to proceed at its sole risk and expense to post the entire bond in support of a preliminary injunction, and such Party shall bear all responsibility for damages, interest, penalties, attorney's fees or other expenses in the Teva Litigation incurred after such Party makes such election to solely post the bond and implement the preliminary injunction.

The Parties agree that paragraphs 6 and 7 of the Section 8.7 Litigation Letter are hereby renumbered as paragraphs 7 and 8, respectively, and that such paragraphs shall remain in full force and effect.

The Parties agree that should any disputes arise relating to the conduct of the Amphastar Litigation or the Teva Litigation, including without limitation, under amended and restated paragraphs 5 and 6 of the Section 8.7 Litigation Letter, the President and CEO of Momenta and Sandoz AG shall promptly meet or discuss by teleconference the dispute and seek in good faith to resolve any differences.

The Parties further agree that this amendment to the Amphastar Litigation Letter and the Section 8.7 Litigation Letter shall be effective as of November 8, 2011 and may be signed in counterparts by each of the Parties.

Except as expressly amended by this letter, the Amphastar Litigation Letter and the Section 8.7 Litigation Letter shall remain in full force and effect.

If the foregoing is consistent with your understanding, please signify your assent by signing both copies of this letter.

Sincerely,

/s/ Bruce Leicher

Bruce A. Leicher
Sr. Vice President and General Counsel

Agreed:

SANDOZ INC.

By: /s/ Don Degolyer
Name: Don Degolyer
Title: President
Date: 11/8/2011

SANDOZ AG

By: /s/ C. Ackermann
Name: Christina Ackermann
Title: General Counsel Sandoz
Date: May 8/2011
By: /s/ Jeff George
Name: Jeff George
Title: Head of Sandoz
Date: Nov 8/2011

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions .

DEVELOPMENT, LICENSE AND OPTION AGREEMENT

BY AND AMONG

MOMENTA PHARMACEUTICALS, INC.,

BAXTER INTERNATIONAL INC.,

BAXTER HEALTHCARE CORPORATION, AND

BAXTER HEALTHCARE SA

DATED AS OF DECEMBER 22, 2011

DEVELOPMENT, LICENSE AND OPTION AGREEMENT

This Development, License and Option Agreement (the “Agreement”), executed the 22nd day of December, 2011 (the “Execution Date”), is made by and among Momenta Pharmaceuticals, Inc., a Delaware corporation (“Momenta”), with a principal place of business at 675 West Kendall Street, Cambridge MA 02142, Baxter International Inc., a Delaware corporation, with a principal place of business at One Baxter Parkway, Deerfield IL 60015-4625 (“BII”), Baxter Healthcare Corporation, a Delaware corporation, with a principal place of business at One Baxter Parkway, Deerfield IL 60015-4633 (“BHC”) and Baxter Healthcare SA, a Swiss corporation with a principal place of business at Thurgauerstrasse 130 Glattpark (Opfikon) 8152 Switzerland (“BHSA” and, together with BII and BHC, “Baxter”). Momenta and Baxter may each be referred to individually as a “Party” or, collectively, the “Parties”.

INTRODUCTION

The Parties desire to collaborate with respect to the development and commercialization of a set number of follow-on versions of reference brand biologic products (a “Follow-On Biologic”, as further defined below) (the “Collaboration”, as further defined below). The Parties, as herein outlined, agree to collaborate, initially, with respect to two (2) Follow-On Biologics, referred to herein as the “Initial Products”. Additional Products (defined below), may be subsequently added to the Collaboration pursuant to the Product Option (defined below).

In consideration of the premises set forth above and the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Momenta and Baxter agree as follows:

ARTICLE 1. DEFINITIONS

Captions; Certain Conventions; Construction. All captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires, (a) words of any gender include each other gender, (b) words such as “herein”, “hereof”, and “hereunder” refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (c) words using the singular shall include the plural, and vice versa, (d) the words “include,” “includes” and “including” shall be deemed to be followed by the phrase “but not limited to”, “without limitation”, “inter alia” or words of similar import, and (e) references to “Article,” “Section,” “subsection”, “clause”, or other subdivision, or Exhibit, without reference to a document are to the specified provision or Exhibit of this Agreement. In the event of any conflict between the operative terms of this Agreement and any Exhibit, the operative terms of this Agreement shall prevail. This Agreement shall be construed as if the Parties drafted it jointly.

- 1.1 “Accounting Standards” shall mean GAAP or IFRS, as applicable, consistently applied.
 - 1.2 “Additional Product(s)” shall have the meaning set forth at Section 2.2.
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1.3 “ Additional Product Notice ” shall have the meaning set forth at Section 2.2(d).

1.4 “ Affiliate ” shall mean any corporation, company, partnership, joint venture and/or firm which controls, is controlled by, or is under common control with a Party. For purposes of the foregoing sentence, “control” shall mean (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

1.5 “ Allocable Legal Expense Share ” shall mean with respect to each Product:

(a) in the event Momenta *has not* elected to receive a Cost/Profit Share under Section 4.7: (i) Momenta [**] percent ([**]%) and (ii) Baxter [**] percent ([**]%), and

(b) in the event Momenta *has* elected to receive a Cost/Profit Share under Section 4.7: the Party’s respective Profit Share Percentages with Momenta’s Profit Share Percentage being as set forth in Section 4.7(b) and Baxter’s being [**].

1.6 “ Baxter Improvement(s) ” shall mean (a) any new Patent Rights or Know-How discovered, derived, acquired or developed in the course of the Collaboration dominated by a pre-existing Patent Right of Baxter, whether or not patentable, and whether discovered, derived, acquired or developed solely by Baxter, jointly by the Parties or solely by Momenta and (b) any Patent Rights or Know-How discovered, derived, acquired or developed in the course of the Collaboration solely by Baxter and/or its Affiliates and/or their respective employees, contractors and/or consultants not dominated by Momenta Patent Rights.

1.7 “ Baxter Intellectual Property ” shall mean all Baxter Know-How, Baxter Patent Rights, and Baxter Improvements.

1.8 “ Baxter Know-How ” shall mean all Know-How that is within the Control of Baxter other than that licensed to Baxter by Momenta pursuant to Article 6 of this Agreement.

1.9 “ Baxter Patent Rights ” shall mean all Patent Rights that are within the Control of Baxter other than Patent Rights licensed to Baxter by Momenta pursuant to Article 6 of this Agreement.

1.10 “ BPCI Act ” shall mean the Biologics Price Competition and Innovation Act of 2009 within the Patient Protection and Affordable Care Act (the “ PPAC Act ”), signed into law in March 2010 as may be subsequently amended after the Execution Date. The PPAC Act amended the Public Health Service Act.

1.11 “ Characterization ” or “ Characterization Activities ” shall mean any non-clinical chemical, physical and biological characterization of a product and the applicable reference product performed for the purpose of determining similarity and/or interchangeability. Characterization may include assessing a product’s chemical composition, physicochemical properties, sequence, subcomposition (*e.g.* , subunit composition, topology, and covalent modifications), stability, integrity and biological activity. Characterization may also include

measuring specific attributes or properties (*e.g.* , specific structures, chemical modifications, chemical connectivities, etc.), aggregate properties, or specific properties, distribution and relative abundance of variants (*i.e.* , mixtures, “glycoforms”, or other variants related to a subset of properties or a description of a product in more comprehensive terms). Characterization may include analysis of components other than the active pharmaceutical ingredient/product (*e.g.* impurities, host cell proteins, etc.). Characterization can be qualitative and/or quantitative. With regard to describing properties and parameters related to the process of making a product, Characterization may include a description of cellular, genetic, metabolic and molecular properties related to a cell line or derivative clones, as well as measurements related to cell growth, transcriptional profile, post-translational modifications, viability, product titer, cellular productivity, media composition, physical parameters (*e.g.* agitation, gas, pH) and metabolic products. The Characterization Activities to be performed as part of the Collaboration shall be as described in the applicable Product Work Plan.

1.12 “ Clinical Development ” shall mean all clinical Development activities necessary to bring a Product to market. The Clinical Development activities to be performed as part of the Collaboration shall be as described in the applicable Product Work Plan.

1.13 “ CMC ” shall mean chemistry, manufacturing and control.

1.14 “ CMC Activities ” shall mean the development activities required to establish the physicochemical properties of the drug substance and the drug product (the “Product” as further defined below) including (a) determining its chemical composition (makeup), stability, solubility; (b) development and qualification/validation of analytical procedures used to characterize the final product as well as intermediates (based on specifications); (c) clinical manufacturing and development of control program; (d) manufacturing, optimization such that the Product can be made at large scale; (e) process validation; and (f) the formulation analysis. The CMC Activities to be performed as part of the Collaboration shall be as described in the applicable Product Work Plan.

1.15 “ Collaboration ” shall mean the Development and Commercialization of, and the conduct of the relevant Legal Activities with respect to, the Products in the relevant countries in the Territory, under this Agreement as described herein and the applicable Product Work Plans.

1.16 “ Collaboration Intellectual Property ” shall mean all Collaboration Know-How and Collaboration Patent Rights. Collaboration Intellectual Property shall exclude Momenta Intellectual Property and Baxter Intellectual Property.

1.17 “ Collaboration Know-How ” shall mean Know-How first discovered, derived or developed in the course of the Collaboration jointly by the Parties and/or their Affiliates and/or their respective employees, contractors or consultants. Collaboration Know-How shall exclude Momenta Know-How and Baxter Know-How.

1.18 “ Collaboration Patent Rights ” shall mean Patent Rights first discovered, derived, or developed in the course of the Collaboration jointly by the Parties and/or their Affiliates and/or their respective employees, contractors or consultants. Collaboration Patent Rights shall exclude Momenta Patent Rights and Baxter Patent Rights.

1.19 “Commercialize” “Commercialization” and “Commercialization Activities” shall mean all activities related to the launch and commercialization of a Product in the respective countries of the Territory. Such Commercialization Activities may include the development and implementation of: (a) a compliant Product publication strategy; (b) a Product education development strategy; (c) a Product registration strategy, including selection, sequencing and filing of individual country or regional Product license applications; (d) commercial manufacture of a Product, including: (i) the development of a commercial inventory and Product supply chain distribution strategy, (ii) the manufacture of commercial inventory, (iii) the manufacture of a delivery device for the Product and (iv) the manufacture of the packaging for the Product; (e) a market access strategy including Product pricing; (f) a Product branding strategy; (g) a Product sales and marketing strategy; (h) a Product safety monitoring program (including all safety reporting and pharmacovigilance activities associated with the Products); (i) a Product post-marketing clinical and label extension strategy; (j) a Product lifecycle management strategy; (k) design, development and implementation of patient support programs and mechanisms; and (l) selling. For avoidance of doubt, (a) through (l) above sets forth examples of activities that may constitute “Commercialization Activities” rather than a list of activities required to be performed by a Party. The Commercialization Activities to be performed as part of the Collaboration for any specific Product shall be as described in the applicable Product Work Plan.

1.20 “Commercialization Costs” shall mean, with respect to a Product, the out-of-pocket costs paid by a Party to a Third Party related to Commercialization and FTE Costs actually incurred, after the Effective Date, in connection with Commercialization of such Product by or on behalf of a Party, in accordance with the applicable Product Work Plan as determined from the books and records of the applicable Party and/or its Affiliates maintained in accordance with the Accounting Standards.

1.21 “Commercialization Plan” shall be a section of the Work Plan and shall be as further described at Section 2.4(b)(iii) herein.

1.22 “Commercial Scale” shall mean the scale of a chemical or biological process for the manufacture of a Product in sufficient quantities to support the projected supply requirements for the marketed Product as of the First Commercial Sale of such Product. Commercial Scale, as it relates to a Product, shall, as appropriate, be further defined in the applicable Product Work Plan.

1.23 “Commercially Reasonable Efforts” shall mean the efforts and resources customarily used by the relevant party to Develop and/or Commercialize a product (as applicable), carrying out such activities in a sustained manner consistent with the efforts that company would use for products with similar market and profit potential and similar scientific, technical, developmental and regulatory risks based on conditions then prevailing. It is anticipated that the level of effort may change over time, reflecting changes in the status of the product and the relevant marketplace.

1.24 “Competing Product” shall mean [**] the relevant country in the Territory using, with respect to the United States of America (“U.S.”), the [**] and with respect to countries in the Territory outside of the U.S., [**]. For purposes of Section 2.3 (Baxter Right of First

Negotiation) only, “Competing Product” shall mean [**]. For purposes of Section 6.6 (Exclusive Collaboration), Competing Product shall also include the [**].

1.25 “Competing Product Notice” shall have the meaning set forth at Section 2.3(b).

1.26 “Confidential Information” shall mean (a) all proprietary information and materials, patentable or otherwise, of a Party which is disclosed by or on behalf of such Party to the other Party pursuant to and in contemplation of this Agreement, including, without limitation, biological or chemical substances, formulations, techniques, methodology, equipment, data, reports, know-how, sources of supply, patent positioning and business plans, including any negative developments, and (b) any other information designated by the disclosing Party to the other Party in writing as confidential or proprietary, whether or not related to making, using or selling a Product. Notwithstanding the foregoing, the term ‘Confidential Information’ shall not include information: (w) which is or becomes generally available to the public other than as a result of disclosure thereof by the receiving Party; (x) which is lawfully received by the receiving Party on a non-confidential basis from a Third Party that is not, to the receiving Party’s knowledge, itself under any obligation of confidentiality or nondisclosure to the disclosing Party or any other Person with respect to such information; (y) which is already known to the receiving Party at the time of disclosure by the disclosing Party; or (z) which can be shown by the receiving Party to have been independently developed by the receiving Party without reference to the disclosing Party’s Confidential Information.

1.27 “Control” shall mean, with respect to any Patent Rights or any item of Know-How, the possession, whether by ownership or license (other than pursuant to this Agreement), by a Party and any of its Affiliates of the ability to grant access and/or a license as provided herein under such item or right without violating the terms of any agreement or arrangement with any Third Party existing before or after the Effective Date.

1.28 “Cost of Goods Sold” shall mean, with respect to a Product, the aggregate of each Party’s cost to commercially manufacture, perform quality activities, test, package and label such Product (including the buildup of commercial inventory), calculated as follows:

(a) For such Product, the cost for manufacturing, performance of quality activities, testing, releasing, packaging, and labeling performed by a Third Party shall equal the costs as invoiced by such Third Party for the manufacture, performance of quality activities, testing, releasing, packaging and labeling of the specified quantity of such Product; and

(b) For such Product, the cost for manufacturing, performance of quality activities, testing, releasing, packaging, and labeling performed by Baxter or its Affiliates shall equal the costs that are incurred by Baxter or its Affiliates in connection with the manufacture, performance of quality activities, testing, releasing, packaging, labeling and delivery to a warehouse(s) designated by Baxter of the specified quantity of such Product, and determined from the books and records of Baxter or its Affiliates maintained in accordance with Baxter’s policies, practices and Accounting Standards. For the avoidance of doubt, Cost of Goods Sold shall include the amount of any royalty payments made to Momenta. Baxter retains the right to modify its policies and practices

to comply with specific changes in the Accounting Standards and as otherwise deemed necessary or appropriate by Baxter. In the event any such modification [**] of Cost of Goods Sold [**], then the Parties [**].

(c) For such Product, the cost for the manufacturing, performance of quality activities, testing, releasing, packaging and labeling performed by Momenta or its Affiliates pursuant to this Agreement shall equal the costs that are incurred by Momenta or its Affiliates in connection with the manufacture, performance of quality activities testing, releasing, packaging, labeling and delivery to a warehouse(s) designated by Momenta of the specified quantity of such Product, and determined from the books and records of Momenta or its Affiliates maintained in accordance with the Accounting Standards and applicable policies and practices as such may be modified from time to time. In the event any such modification [**] of Cost of Goods Sold [**].

(d) General Guidelines.

(i) Cost of Goods Sold must be calculated with reasonable approximation to actual costs (use of standard cost plus variances (purchase price, production, etc.) to achieve actual costs), including provisions for and subsequent charges to obsolescence. Cost of Goods Sold shall include, but not be limited to labor, overhead, materials, discards, plant depreciation, plant utilization, quality-related testing, releasing, stability samples, packaging & labeling and other cost of goods (*e.g.* discard provisions for expired material write-offs).

(ii) The expected costs to manufacture, perform quality activities, test, release, package, label and deliver to a warehouse(s) shall include the manufacturing plant labor, an allocation of plant overhead expenses (examples may include insurance, facility, support staff personnel, etc.), materials and supplies, maintenance, discards, depreciation and amortization, royalties, quality, and other costs attributable to a Product as applicable.

(iii) If Third Party Payments for licensed Third Party Patent Rights or Know-How related to the commercial manufacture, performance of quality activities, testing, releasing, packaging and/or labeling are payable with respect to a Product after First Commercial Sale of such Product in the relevant country in the Territory, such amounts, to the extent such Third Party Payments are not otherwise expressly allocated among the Parties for payment under Section 4.4, below, [**] such Third Party Payments [**]. With respect to Products which are subject to a Cost/Profit Share under Section 4.7, reimbursement of such Third Party Payments [**] in accordance with the Profit Share Percentage.

(iv) The Parties shall discuss in good faith at the JSC [**] with respect to any [**] or other [**], whether such facility is owned by [**] or a Third Party, that will be utilized in the manufacture of a Product. If [**] it will [**] or [**] a facility with [**] relative to the good faith projected [**], any decision [**] for such facility [**] in the computation of Cost of Goods Sold [**].

1.29 “Cost Share” shall mean the sum of (a) the Commercialization Costs and (b) the Development Expenses to the extent that such Commercialization Costs and the Development Expenses are incurred following Momenta’s Cost/Profit Share Election, all multiplied by the Profit Share Percentage elected by Momenta.

1.30 “Develop”, “Development” and “Development Activities” shall mean with respect to a product, all activities related to or in furtherance of the creation or scientific improvement of such product, or are related to or in furtherance of the Regulatory Approval of such product, whether such activities are conducted prior to the filing of a regulatory application for such product in any country in the Territory or thereafter. Development Activities may include: (a) Characterization of such product; (b) creation and selection of a cell line; (c) preclinical and, if applicable, clinical (in human) studies, bioequivalence studies, development of analytical assays, stability studies and quality analysis/quality control development, data management, review and engagement of CROs, document preparation, and other administrative activities associated with a clinical testing program; (d) development and implementation of a regulatory and legal strategy to address whether to file a biologics application under Section 351(a) or an abbreviated application under Section 351 (k) of the BPCI Act, and depending on the pathway selected, whether and how the Parties plan to utilize the patent resolution process under the 351(k) pathway; (e) development and implementation of the Product manufacturing process and strategy, including selection of manufacturing facilities at each scale (including Commercial Scale); (f) development and implementation of a process validation strategy; (g) formulation (for drug substance and drug product, as well as associated stability studies); (h) development and design of a delivery device for the Product; (i) development and design of the Product packaging; (j) statistical analysis; (k) pre-launch regulatory affairs; and (l) research and development expenses associated with Product development after Regulatory Approval (such as post-marketing studies). For the avoidance of doubt, the terms ‘Develop’, ‘Development’ and ‘Development Activities’ shall not include Commercialization Activities. For avoidance of doubt, (a) through (l) above sets forth examples of activities that would constitute “Development Activities” rather than a list of activities required to be performed by a Party. The Development Activities to be performed as part of the Collaboration for any specific Product shall be as described in the applicable Product Work Plan.

1.31 “Development Expenses” shall mean, with respect to a Product, the costs actually incurred by or on behalf of a Party, including all FTE Costs and out-of-pocket costs paid by a Party to Third Parties (collectively) after the Effective Date in connection with the Development of such Product, in accordance with the relevant Product Work Plan as determined from the books and records of the applicable Party and/or its Affiliates maintained in accordance with the Accounting Standards and each Party’s policies and practices as such may be modified from time to time.

1.32 “Effective Date” shall mean the HSR Clearance Date, as defined in Section 12.12.

1.33 “Election Notice” shall have the meaning set forth at Section 2.2(a).

1.34 “Enforcement Litigation” shall have the meaning set forth at Section 5.4(c).

1.35 “Exercise Notice” shall have the meaning set forth at Section 2.2(d).

1.36 “FDA” or “Food and Drug Administration” shall mean the U.S. Food and Drug Administration or any successor entity thereto.

1.37 “Field” shall mean human use for all therapeutic indications.

1.38 “First Commercial Sale” shall mean, with respect to a Product, the first sale by Baxter, its sublicensee or any of their respective Affiliates to a Third Party following receipt of Regulatory Approval in the country of sale.

1.39 “Follow-On Biologic” or “FOB” shall mean a biologic product that is developed by the Parties, with the amino acid sequence identical to the reference brand biologic, that through Characterization and Development is (a) intended to have highly similar or indistinguishable physical, chemical, biological and clinical attributes relative to the reference brand biologic and (b) is eligible for review and approval by the FDA under Section 351(k) of the BPCI Act or equivalent EU guidelines, regardless of whether approval is sought under Section 351(k) or 351(a) or the equivalent EU guidelines for commercial purposes.

1.40 “FTE” shall mean a full time equivalent person year (consisting of a total of one thousand eight hundred (1,800) hours per year) of work on or directly related to the Collaboration.

1.41 “FTE Costs” shall be as determined by the JSC at the initial JSC meeting, as such is contemplated in Section 3.3, such FTE Costs to be derived in accordance with the Accounting Standards. Beginning [**] and each January 1 thereafter during the Term, the FTE Costs as initially determined by the JSC shall be increased by the lesser of: (a) [**] percent ([**]%) and (b) the percentage change in the [**] over the prior year.

1.42 “GAAP” shall mean U.S. Generally Accepted Accounting Principles.

1.43 “General & Administrative Costs” or “G & A Costs” shall mean non-sales personnel costs (excluding manufacturing personnel costs) and other overhead costs that are proportionally allocated to the Product. G & A Costs shall be a rate, calculated as a percentage of Net Sales, as determined by the JSC on a product-by-product basis based upon the projected Product budget. Such rate shall be determined no later than [**] months following [**] of such Product if Momenta has exercised its option for a Cost/Profit Share. The JSC shall, on an annual basis, adjust the rate to reflect actual budgets for the following year. G & A Costs shall be included in Marketing and Selling Costs.

1.44 “GMP” or “Good Manufacturing Practice” shall mean the current good manufacturing practice regulations of the FDA as described in the U.S. Code of Federal Regulations or any applicable corresponding foreign regulations or their respective successor regulations.

1.45 “IFRS” shall mean International Financial Reporting Standards.

1.46 “IND Acceptance” shall mean, with respect to a Product, the earlier to occur of the date that (a) the Investigational New Drug (“IND”) exemption or its equivalent becomes effective in the U.S. or the EU; (b) written notice of a waiver of the need to file an IND, or

waiver of its equivalent in the U.S. or the EU becomes effective; or (c) authorization is obtained from the applicable Regulatory Authority in the U.S. or the EU to initiate dosing in humans, based on such Regulatory Authority's review of analytical data comparing such Product to the reference brand product. For avoidance of doubt, the written notice referred to in subsection (b) above may be in the form of a letter from the relevant Regulatory Authority approving the development plan of the Parties that does not require human clinical trials or an actual written waiver of an IND.

1.47 “Initial Press Release” shall have the meaning set forth at Section 7.2 herein.

1.48 “Initial Products” shall have the meaning set forth in the Introduction section above, as such are more fully described at Section 2.1.

1.49 “Joint Steering Committee” or “JSC” shall have the meaning set forth in Section 3.1.

1.50 “Know-How” shall mean information and materials, including, without limitation, ideas, concepts, discoveries, inventions, developments, improvements, know-how, expertise, trade secrets, designs, devices, equipment, process conditions, production processes and designs, specifications, computer programs, formulas, techniques, methods, procedures, assay systems and applications, experimental results, data (including, without limitation, analytical, toxicological, pharmacological, clinical, bioequivalence, and stability data), documentation, and reports, whether patentable or otherwise.

1.51 “Launch” shall mean, with respect to any Competing Product, the first commercial sale of such Competing Product unless, within sixty (60) days of such first commercial sale, the product is no longer being offered for sale (whether as a result of legal action or otherwise).

1.52 “Laws” shall mean all applicable laws, statutes, rules, regulations, orders, judgments, injunctions, ordinances or other pronouncements having the binding effect of law of any Regulatory Authority or other governmental authority, and any rules of any national securities exchanges or securities listing organizations, in the applicable country in the Territory.

1.53 “Legal Activities” shall mean legal work and advice relating to the Collaboration including, but not limited to: (a) Patent Activities; (b) regulatory filings and regulatory strategy; (c) citizen's petitions proceedings (including filings, appeals and related litigation); (d) patent exchange and litigation under the BPCI Act (or other similar laws, rules or regulations, as applicable to one or more Products); (e) litigation strategy; and (f) governmental inquiries and investigations.

1.54 “Legal Expenses” shall mean out-of-pocket expenses associated with Legal Activities. For the avoidance of doubt, the term ‘Legal Expenses’ shall not include [**] or [**] costs or expenses with respect to Legal Activities conducted in support of the Collaboration, and each Party shall be solely responsible for and pay its [**] costs and expenses. For avoidance of doubt, Legal Expenses includes the costs of [**] or [**] in connection with Enforcement Litigation, and any resulting damages payable to Third Parties in connection with Enforcement Litigation.

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1.55 “Legal Expense Cap” shall mean, for any Product, [**] Dollars (USD\$[**]).

1.56 “Major Countries” shall mean the U.S., [**], the United Kingdom, France, Germany, Spain, Italy, [**].

1.57 “Marketing and Selling Costs” shall mean a rate (calculated as a percentage of Net Sales) as determined by the JSC on a Product-by-Product and country-by-country basis based upon the projected Product budget as approved by the JSC. The rate shall be determined no later than [**] following IND Acceptance if Momenta has exercised its option for a Cost/Profit Share. The JSC shall, if applicable, create two lists reflecting different ‘Marketing and Selling Costs’ rates based upon the Regulatory Approval status of the Product (with pharmacy substitutability or without pharmacy substitutability) and the Marketing and Selling Costs rate utilized in the calculation of the Profit Share shall be the rate reflecting the actual status of pharmacy substitutability for the Product in the applicable country in the Territory. The JSC shall, on [**] basis, adjust these rates to reflect [**] for the following year. Marketing and Selling Costs shall include G&A Costs.

1.58 “Mechanism of Action” shall mean that the relevant Third Party FOB binds to the same antigen as the Product.

1.59 “Minimum Development Criteria” shall mean, with respect to any product, that Momenta has, in connection with its Development efforts, (a) delivered [**], (b) achieved [**] of the product [**], and (c) has delivered [**] consistent with that conducted [**] as of the Execution Date.

1.60 “Momenta Improvement(s)” shall mean (a) any new Patent Rights or Know-How discovered, derived, acquired or developed in the course of the Collaboration dominated by a pre-existing Patent Right of Momenta, whether or not patentable, and whether discovered, derived, acquired or developed solely by Momenta, jointly by the Parties or solely by Baxter and (b) any Patent Rights or Know-How discovered, derived, acquired or developed in the course of the Collaboration solely by Momenta and/or its Affiliates and/or their respective employees, contractors and/or consultants not dominated by Baxter Patent Rights.

1.61 “Momenta Intellectual Property” shall mean all Momenta Know-How, Momenta Patent Rights and Momenta Improvements.

1.62 “Momenta Know-How” shall mean all Know-How that is within the Control of Momenta other than that licensed to Momenta by Baxter pursuant to Article 6 of this Agreement.

1.63 “Momenta Patent Rights” shall mean all Patent Rights that are within the Control of Momenta other than Patent Rights licensed to Momenta by Baxter pursuant to Article 6 of this Agreement.

1.64 “Naming” or as a verb “Name” or “Named” shall mean, with respect to any Additional Product, that such Additional Product has been selected by Baxter and has been identified to Momenta in writing as an Additional Product.

1.65 “Net Sales” shall mean, with respect to a Product, the gross revenues invoiced by Baxter or its Affiliates or sublicensees to Third Parties (whether an end-user, a distributor or otherwise) for sales of such Product within the Territory, less the following deductions, all as determined from the books and records of Baxter, its Affiliates or sublicensees (or, in the event Momenta Commercializes a Product as allowed for at Section 2.7(b) or Section 10.6 herein, references to Baxter herein shall be replaced by “Momenta”) maintained in accordance with the Accounting Standards:

- (a) customary trade and quantity discounts actually allowed and taken;
- (b) amounts actually allowed or credited due to returns of Products previously sold as reflected in written invoices (and not to exceed the original invoice amount);
- (c) shipping, freight and insurance, to the extent separately invoiced and charged;
- (d) credits, allowances and rebates actually given pursuant to federal, state and/or government-mandated programs, which require a manufacturer/distributor rebate (including Medicare and Medicaid); and
- (e) value added or import/export taxes, sales taxes, excise taxes or customs duties, to the extent applicable to such sale, and included in the invoice in respect of such sale and actually paid.

In the case of any sale of a Product [**].

In the case of any sale of a Product between or among Baxter or its Affiliates or sublicensees for resale, Net Sales shall be calculated as above only on the value charged or invoiced on the first arm’s length sale thereafter to a Third Party other than a sublicensee. Product provided to any Third Party in connection with any clinical trials shall not be considered for purposes of calculating Net Sales.

If any Product is sold in combination with one or more other products (e.g. a delivery device) or active ingredients which are not the subject of this Agreement (as used in this definition of Net Sales, a “Combination”), then the gross amount invoiced for that Product shall be calculated by multiplying the gross amount invoiced for such Combination by the fraction $A/(A+B)$, where “A” is the gross amount invoiced for the Product sold separately and “B” is the gross amount invoiced for the other active ingredient(s) sold separately. In the event that the other active ingredient is not sold separately, then the gross amount invoiced for that Product shall be calculated by multiplying the gross amount invoiced for the Combination by the fraction A/C , where “A” is the gross invoice amount for the Product, if sold separately, and “C” is the gross invoice amount for the Combination. In the event that no such separate sales are made, Net Sales for royalty determination shall be determined by the Parties in good faith. Where (A) the consideration for Products includes any [**]; or (B) Products are transferred by the selling Party, its Affiliate, or a respective sublicensee, in any manner other than an arms-length, invoiced sale, the Net Sales [**] shall be the [**] for the period in question in the applicable country of the Territory. The [**] shall be determined, wherever possible, by reference to the [**] in the Territory.

1.66 “ Option Payment ” shall have the meaning set forth at Section 2.2(d).

1.67 “ Option Period ” shall have the meaning set forth at Section 2.2(d).

1.68 “ Patent Activities ” shall mean all activities of the Parties with respect to freedom to operate, and the preparation, filing, prosecution, maintenance, enforcement and defense of the Momenta Patent Rights licensed under Section 6.1, the Baxter Patent Rights licensed under Section 6.2 and Collaboration Patent Rights including activities before the U.S. Patent and Trademark Office, and international patent offices as well as litigation in courts in the U.S. and other countries in the Territory.

1.69 “ Patent Rights ” shall mean all patents (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, invalidations, supplementary protection certificates and patents of addition) and patent applications (including all provisional applications, continuations, continuations-in-part and divisionals) and, all foreign counterparts of the foregoing, or as applicable portions thereof or individual claims therein.

1.70 “ Person ” shall mean any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Regulatory Authority or any other entity not specifically listed herein.

1.71 “ Phase II Clinical Trial ” shall mean a controlled clinical trial of a pharmaceutical/biologic product in human patients to evaluate its safety and efficacy in the proposed therapeutic indication, which may be a single dose or regimen and/or multiple doses and/or regimens, which may be conducted at multiple centers and while not a customary Phase II study, may be suitable to obtain Regulatory Approval. A Phase II Clinical Trial generally has hundreds of subjects (or less) and is defined in the U.S. as meeting the requirements set forth in 21 C.F.R 312.21. A Phase II Clinical Trial is not a Phase III Clinical Trial simply because it enables Regulatory Approval.

1.72 “ Phase III Clinical Trial ” shall mean a large scale, fully-powered, pivotal, multi-center, human clinical trial (but specifically excluding any Phase II Clinical Trials and any dose ranging and/or proof of concept studies) to be conducted in a number of patients estimated to be sufficient (hundreds or thousands of subjects per indication) to primarily establish the efficacy and safety of a pharmaceutical/biologic product in the indication being investigated and at a standard suitable to obtain Regulatory Approval.

1.73 “ Process Engineering ” or “ Process Engineering Activities ” shall mean the design of a biological process (which may include both upstream cell fermentation process and downstream purification, fill finish) and/or chemical process to manufacture a biological product with pre-specified attributes. These attributes may include product yield, biophysical and physico-chemical properties, specific chemical structures/modifications related to product glycosylation, protein sequence, amino acid modifications, tertiary structure, subunit stoichiometry, etc., aggregate properties, distribution of variants (*e.g.* , “glycoforms”), biological activity, pharmacological properties, product stability, integrity, and immunogenicity. These attributes may be defined both in qualitative (present or absent) or quantitative terms, the latter being described for example by an absolute amount, a relative abundance, or within a specified

range. Process Engineering also means the engineering of a cell line (*i.e.* , cell line development) and/or choice of clone derived from this cell line (*i.e.* , “clonal selection”) with the intent to produce a product with pre-specified attributes. The Process Engineering Activities to be performed under this Agreement shall be as described in the applicable Product Work Plan.

1.74 “ Product(s) ” shall mean the Initial Products and the Additional Products; the latter effective as of Baxter’s exercise of the Additional Product Option. Each individually a “ Product ” and, collectively, the “ Products ”.

1.75 “ Product Option ” shall have the meaning set forth at Section 2.2(d) .

1.76 “ Profit(s) ” shall mean, with respect to a quarter during which Baxter, its Affiliates and/or distributors is selling a Product in a country(ies) in the Territory, Net Sales for such Product less (a) Marketing and Selling Costs and (b) Cost of Goods Sold for the units of such Product sold (regardless of whether such Product is rejected, returned or recalled).

1.77 “ Profit Share ” shall mean Profits multiplied by the elected Profit Share Percentage.

1.78 “ Profit Share Election Notice ” shall have the meaning set forth at Section 4.7(a) .

1.79 “ Profit Share Election Period ” shall have the meaning set forth at Section 4.7 .

1.80 “ Profit Share Percentage ” shall have the meaning set forth at Section 4.7(b) .

1.81 “ Quality Management Systems ” or “ QMS ” shall mean formalized business practices that define management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill product/service requirements, customer satisfaction, and continual improvement.

1.82 “ Regulatory Approval ” shall mean, with respect to a country, all approvals, licenses, registrations, and regulatory authorizations required to make, store, import, transport, market and sell a Product in such country as granted by the relevant Regulatory Authority. For countries in the Territory where Regulatory Authority approval is required for pricing or reimbursement for Product, Regulatory Approval shall not be deemed to occur until such pricing or reimbursement approval is obtained.

1.83 “ Regulatory Authority ” shall mean the FDA or any other counterpart or applicable government authority, court, tribunal, arbitrator, agency, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any state, province, county, city or other political subdivision thereof or (c) any supranational body responsible for granting applicable Regulatory Approvals.

1.84 “ Royalty Offset ” shall have the meaning set forth at Section 4.7(d) herein.

1.85 “ Selected Third Party Product ” shall have the meaning set forth at Section 2.2(f)(ii) .

1.86 “Selected Third Party Product Election Notice” shall have the meaning set forth at Section 2.2(f)(ii).

1.87 “Sole Interchangeable Product” shall mean that the Product is the only commercially available FOB product in a given country in the Territory that has received a designation, or its equivalent, from the applicable Regulatory Authority, that pharmacists can substitute the Product for the reference product without obtaining a prescriber’s consent (e.g. , with respect to the U.S., an interchangeable biological product under Section 351(k) of the BPCI Act).

1.88 “Sublicense Revenue” shall mean all consideration received by Baxter or its Affiliates with respect to rights granted to a Third Party(ies) to Develop or Commercialize a Product(s) for sale in the relevant country in the Territory, but excluding: (a) consideration received by Baxter or its Affiliates as payments for actual direct costs for performing Development or Commercialization Activities undertaken by Baxter or its Affiliates for, or in collaboration with, such Third Party(ies) or their Affiliates; (b) consideration received by Baxter and/or its Affiliates from such Third Party(ies) or their Affiliates as the purchase price for Baxter’s or any of its Affiliates’ debt or equity securities, except that consideration that exceeds the fair market value of such debt or equity securities shall not be so excluded; and (c) consideration paid by such Third Party(ies) to Baxter or its Affiliates to purchase such Product(s) (provided, however, that any consideration greater than the applicable Cost of Goods Sold shall not be so excluded).

1.89 “Technical De-Risking Criteria” shall be as set forth in Exhibit 1.89 and Section 2.4(e)(iv).

1.90 “Technology Transfer” shall mean all activities undertaken to transfer the manufacture of a Product (regardless of the manufacturing scale) from one party (whether a Third Party or a Party) to another party (again, whether a Third Party or a Party). Section 2.8 and Exhibit 1.90 set forth the rights and responsibilities of the Parties with respect to Technology Transfer.

1.91 “Territory” shall mean with respect to the Products, all countries of the world. Notwithstanding anything contained in this Agreement to the contrary, any references to ‘Territory’ with respect to Baxter’s Commercialization obligations is not intended to, nor shall it be construed to imply, that Baxter is obligated to Commercialize any Product in all countries or geographies throughout the world.

1.92 “Third Party” shall mean any Person other than Momenta or Baxter or any Affiliate of either Party.

1.93 “Third Party Additional Product” shall have the meaning set forth at Section 2.2(f)(i).

1.94 “Third Party Additional Product Notice” shall have the meaning set forth at Section 2.2(f)(i) herein.

1.95 “Third Party Payments” shall mean, with respect to a Product in the relevant country in the Territory, any royalties, license fees, maintenance fees or other monetary payments made by a Party or its Affiliates to any Third Party in consideration of a license(s) under the applicable Third Party Patent Rights or Know-How or other intellectual property rights, when such license is determined [**].

1.96 “Work Plan” or “Product Work Plan” shall mean, with respect to a Product, the Product specific plan, developed and approved by the JSC on an annual basis and modified through the year, outlining the Development and Commercialization (including the pursuit of Regulatory Approval) of such Product in the Territory. The Commercialization Plan shall be a section of the Work Plan.

ARTICLE 2. DEVELOPMENT AND COMMERCIALIZATION OF THE PRODUCTS

2.1 Initial Products. The Parties intend and agree to Develop and Commercialize the Initial Products as outlined in this Agreement and in accordance with the applicable Work Plan for each Product. Such ‘Initial Products’, which are FOBs, are: (a) [**] referred to as [**] for which [**] is the reference brand product and (b) [**] referred to as [**] is the reference brand product.

2.2 Additional Products. Baxter shall have an option (each a “Product Option”), during the Option Period, to include as Products in the Collaboration, in addition to the two (2) Initial Products, up to four (4) additional products (once Named, each an “Additional Product” or collectively, the “Additional Products”).

(a) Selection of the Additional Products. The period during which all Additional Products must be Named (the “Naming Period”) shall commence on the Effective Date of the Agreement and end on the third (3rd) anniversary of the Effective Date. Each of the additional products must be Named by Baxter, in writing, upon the earlier to occur of: (i) [**] of the Naming Period (*i.e.* any un-Named potential Additional Products would need to be Named at the end of the Naming Period or Baxter will lose the rights thereto) or (ii) [**] days after receiving written notice from Momenta that Momenta has [**] of a new FOB product to meet the [**] (an “Election Notice”) (*i.e.* such Election Notice shall indicate Momenta’s suggestion for a product(s) to be Named as an Additional Product(s)). Except as provided for in Section 2.2(b) and Section 2.2(f) below, once an Additional Product is Named by Baxter [**] to [**] without [**]. Each of the Additional Products must be [**].

(b) Additional Products - Development Obligations of Momenta. Momenta shall use Commercially Reasonable Efforts to Develop, at its sole cost and expense, each of the Additional Products Named by Baxter until each such Additional Product [**]. Prior to Momenta engaging in any Development work on an Additional Product, the Parties shall consult and discuss Momenta’s Development plan for such Additional Product within the JSC.

In the event that Momenta determines it [**] with respect to an Additional Product Named by Baxter, [**], Momenta shall provide written notice to Baxter of such determination. Following Baxter's receipt of such notice from Momenta, such Named Additional Product shall no longer be a Named Additional Product and Baxter shall have the right to Name another product as an Additional Product, and Momenta shall thereafter have the right, subject to the terms of this Agreement including, to the extent applicable, the limited licenses granted herein, to research, develop, manufacture, commercialize or license a Third Party to research, develop, manufacture or commercialize such former Additional Product. In the event that, at the time of Baxter's receipt of such notice from Momenta regarding its [**], Baxter has Named all four Additional Products, Baxter's right to Name another product as an Additional Product shall be restricted to the extent Momenta has already entered into an agreement with a Third Party for the development of any such potential Additional Product.

(c) Additional Product Naming Period.

(i) Extension of the Naming Period.

(1) Baxter shall have the option to extend the Naming Period for an additional [**] period (to run from the end of the original termination date of the Naming Period as outlined in Section 2.2(a) above) to Name any as yet un-Named Additional Products. Such option to extend the Naming Period shall terminate upon Baxter's Naming of the final Additional Product; provided, however, that if [**] of the [**], Momenta determines that it [**] as contemplated in Section 2.2(b), the terms of the second paragraph of Section 2.2(b) shall apply and Baxter shall have the ability to Name an alternative Additional Product.

(2) To extend the Naming Period for a particular product, Baxter must provide Momenta with a written extension notice at least [**] prior to the end of the [**]. Such extension notice shall indicate the [**]. For each Naming Period extension so notified, Baxter shall pay to Momenta Five Million Dollars (USD\$5,000,000) within [**] of the [**].

(3) If the Naming Period expires and Baxter has failed to provide the written extension notice as required above or if Baxter does not pay the relevant extension payment within the timeframe described in the immediately preceding paragraph, the Naming Period(s), with respect to the un-Named potential Additional Product (s), will terminate.

(4) Notwithstanding the foregoing, the Naming Period shall be automatically extended (and Baxter shall not be obligated to make any payment for such extension) for a period of not less than [**] if, within the [**] prior to [**], Momenta has yet to provide Baxter with an Election Notice as provided for at Section 2.2(a) with respect to one or more as yet un-Named Additional Products so as to allow Baxter to make an informed decision with respect to the Naming of such one or more as yet un-Named

Additional Products. The Naming Period shall thereafter continue to be extended for periods of not less than [**] if Momenta again fails to provide such Election Notice(s).

(d) [**] of the [**]; Exercise of the Product Option. Upon [**] of the [**] with respect to an Additional Product, Momenta shall notify Baxter in writing (such notice with respect to each Additional Product, an “Additional Product Notice”). Following Baxter’s receipt of the Additional Product Notice, Baxter shall have the right to include a Named Additional Product as a Product in the Collaboration (the “Product Option”). Baxter may exercise the Product Option with respect to such Additional Product by providing written notice to Momenta of its desire to include the Additional Product under the Agreement as a Product (the “Exercise Notice”). The Exercise Notice must be received by Momenta within [**] following Baxter’s receipt of an Additional Product Notice with respect to such Additional Product (the “Option Period”). Within [**] following delivery of the applicable Additional Product Exercise Notice, Baxter shall pay to Momenta [**] Dollars (USD\$[**]) (the “Option Payment”). Except as set forth in Section 2.2(f)(ii), upon Baxter’s exercise of the Product Option with respect to such Additional Product named in the Exercise Notice and payment of the Option Payment with respect to such Additional Product, such Additional Product shall be treated as a Product under the terms of the Agreement.

(e) Failure to Exercise the Product Option. In the event Baxter fails to exercise the Product Option by providing the Exercise Notice within [**] following receipt of the Additional Product Notice as outlined in Section 2.2(d) above or if Baxter fails to pay the Option Payment within the timeframe described above, the Product Option, with respect to such Additional Product, shall expire (subject to Baxter’s right to cure such timely failure to make the Option Payment), and such product shall not be considered a Product and shall no longer be considered an Additional Product, and Momenta shall thereafter have the right, subject to the terms of this Agreement including, to the extent applicable, the limited licenses granted herein, to research, develop, manufacture, commercialize or license a Third Party to research, develop, manufacture or commercialize such former Additional Product. For the avoidance of doubt, [**] as provided for in Section 2.2(b) above and Section 2.2(f) below. If Baxter fails to exercise the Product Option with respect to a Named Additional Product [**], Baxter shall not have the right to Name another Additional Product to replace the Additional Product for which it failed to exercise the Product Option.

(f) Third Party Additional Product.

(i) Generally. Commencing [**] following the Effective Date of the Agreement and continuing until [**] to occur of (a) the end of the Naming Period or (b) when Baxter has Named all four (4) Additional Products, if Momenta receives a bona fide offer from a Third Party for the Third Party to develop or commercialize a FOB [**] (*i.e.* a potential Additional Product candidate) developed or to be developed by Momenta that includes financial terms (“Third Party Additional Product”), Momenta shall provide written notice to Baxter of such offer (“Third Party Additional Product Notice”), and shall, to the extent not

otherwise prohibited by the terms of its confidentiality agreement with such other Third Party, include in such Third Party Additional Product Notice a redacted copy of the offer itself (but Momenta shall have no obligation to disclose the identity of such Third Party or the financial terms of such offer). Following Baxter's receipt of the Third Party Additional Product Notice, Baxter shall have [**] to deliver an Exercise Notice to Momenta, exercising a Product Option with respect to such Third Party Additional Product, or in the absence of such notice, Baxter shall forfeit its right to Name that FOB product as an Additional Product and to include it as a Product in the Collaboration. In the event Baxter delivers the Exercise Notice with respect to the Third Party Additional Product, Baxter shall pay to Momenta the Option Payment within [**] of delivering the Exercise Notice, and such Third Party Additional Product shall become a Product under the Agreement. If Baxter fails to pay the Option Payment with respect to the Third Party Additional Product within the timeframe described above, it shall forfeit its right to Name that FOB product as an Additional Product and to include it as a Product in the Collaboration.

(ii) During the [**], if Baxter delivers to Momenta an Exercise Notice with respect to a Third Party Additional Product, thereby including such Third Party Additional Product as Product in the Collaboration (the "Selected Third Party Product"), [**] with respect to each such Selected Third Party Product, to [**] (other than an FOB product for which Baxter forfeited its rights pursuant to Section 2.2(b), Section 2.2(e), Section 2.2(f) and Section 2.2(g), as a Product [**] such Selected Third Party Product. [**], Momenta shall thereafter have the right, subject to the terms of this Agreement, to the extent applicable, including, to the extent applicable, the limited licenses granted herein, to research, develop, manufacture, commercialize or license a Third Party to research, develop, manufacture or commercialize such [**] upon the earlier to occur of: (a) [**] following Momenta's receipt of the Exercise Notice from Baxter with respect to such Selected Third Party Product or (b) [**] after Baxter's receipt of notice from Momenta that Momenta has [**] (the "Selected Third Party Product Election Notice"). Notwithstanding the payment obligations set forth in Section 2.2(d), during the [**] period following the Effective Date of the Agreement, Baxter shall not be obligated to [**] with respect to any Third Party Additional Product for which it has delivered an Exercise Notice until [**] following [**] that such Product [**].

(g) [**].

(i) [**] Efforts. If Baxter (A) [**] a [**] outside the scope of the Collaboration, whether a FOB product or reference brand product, or (B) undertakes any efforts with a Third Party to [**] (in either case, a "[**]"), Baxter shall immediately and automatically forfeit its right to Name such [**] as an Additional Product under the Agreement and Momenta shall thereafter have the right, subject to the terms of this Agreement including, to the extent applicable, the limited licenses granted herein, to directly or indirectly research, develop, manufacture, or commercialize a FOB product of or any derivative of such [**],

or to license a Third Party to research, develop, manufacture or commercialize a FOB product of or any derivative of such [**].

(ii) [**]. If Baxter [**] for [**] outside the scope of the Collaboration, whether a FOB product or reference brand product, [**] such a product (the “[**]”), Baxter shall have a period of [**] to determine if it intends to [**]; provided, however that if the [**] is, at the time of the [**] a marketed product (*i.e.* has been sold commercially in an arms-length transaction for therapeutic use) the period shall be [**]. If, upon the [**] anniversary (or [**] anniversary in the case of a marketed product) of the transaction in which [**] the relevant [**] Baxter is still in control of such [**], Baxter shall immediately and automatically forfeit its right to Name such [**] as an Additional Product under the Agreement and Momenta shall thereafter have the right, subject to the terms of this Agreement including, to the extent applicable, the limited licenses granted herein, to directly or indirectly research, develop, manufacture, or commercialize a FOB product of or any derivative of such [**], or to license a Third Party to research, develop, manufacture or commercialize a FOB product of or any derivative of such [**]. In the event the [**] becomes marketed subsequent to Baxter’s [**] of such [**] and prior to the expiration of such [**] period, Baxter shall immediately and automatically forfeit its right to Name such [**] as an Additional Product as provided for in Section 2.2(g) above.

2.3 Momenta Competing Product; Baxter Right of First Negotiation.

(a) For a period of three (3) years following IND Acceptance of the first Product, Baxter shall have a right of first negotiation (the “Right of First Negotiation” or “ROFN”) if: (i) Momenta intends to develop (either for itself or for a Third Party) a Competing Product (such ROFN is not available with respect to a FOB product for which Baxter forfeited its rights pursuant to Sections 2.2(b), 2.2(e), 2.2(f) or 2.2(g)), and (ii) all four Additional Products have been Named or all Product Options have expired.

(b) Upon Baxter’s receipt of written notification from Momenta of its intent to develop such Competing Product(s) (the “Competing Product Notice”), Baxter shall have [**] to provide written notice to Momenta of its desire to enter into good faith negotiations to reach agreement on a partnering transaction with respect to such Competing Product(s) referenced in the applicable Competing Product Notice. If Baxter notifies Momenta of its interest in such Competing Product(s), the Parties shall commence good faith negotiations toward the execution of a partnering transaction with respect to such Competing Product(s), but if Baxter and Momenta have not executed a written agreement reflecting such a transaction with respect to such Competing Product(s) within [**] of Baxter’s receipt of the Competing Product Notice, Momenta shall have the right, subject to the terms of this Agreement including, to the extent applicable, the limited licenses granted herein, to research, develop, manufacture or commercialize such Competing Products or license a Third Party to research, develop, manufacture or commercialize such Competing Product(s).

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2.4 Responsibility for Development and Commercialization of the Products.

(a) Efforts and Cooperation. The Parties shall, with respect to each Product, use Commercially Reasonable Efforts to carry out the Development and Commercialization Activities contemplated hereunder. Without limiting the foregoing, at a minimum, each Party shall devote the resources, as set forth in the applicable Product Work Plan.

(b) Work Plans.

(i) A preliminary Work Plan with respect to each of the Initial Products shall be developed and agreed upon by the JSC, as provided for below, within [**] of the Effective Date. With respect to the remaining Products contemplated hereunder, a preliminary Product applicable Work Plan shall be developed within [**] of Momenta’s receipt from Baxter of the Exercise Notice with respect to such Additional Product (*i.e.* Baxter’s exercise of the Product Option with respect to such Additional Product, as provided for at Section 2.2(d) above or the Selected Third Party Product Exercise Notice pursuant to Section 2.2(f)(i)).

(ii) Each Work Plan shall include, as appropriate: (A) specific objectives of the Collaboration during the applicable year; (B) the specific activities to be performed by each Party, or by Third Parties, in support of the Development and Commercialization of the Products for the applicable year; (C) contemplated timelines associated with Development and Commercialization Activities (including contemplated timelines for applicable regulatory filings); (D) a budget reflecting the resources (including FTEs for each Party) to be assigned and amounts anticipated to be expended by each Party in support of the Development and Commercialization of the Products; (E) a rolling five (5) year plan with a complete Product income statement (product P&L), which includes (A)-(D) above.

(iii) The Commercialization plan will initially be a high-level rolling [**] forecast (the “Commercialization Plan”) and will be provided within [**] of the Effective Date with respect to the Initial Products and within [**] after Momenta’s receipt of the Exercise Notice from Baxter with respect to the inclusion of an Additional Product as a Product in the Collaboration and updated annually as part of the Work Plan. Commencing no later than [**] prior to submission of an application for Regulatory Approval for each Product in a Major Country, Baxter shall submit to the JSC a more detailed Commercial Plan as part of the Work Plan section for review and approval by the JSC (such detail taking into account the time that will elapse until First Commercial Sale of the Product).

(c) Momenta Responsibilities. In general, subject to the applicable Product Work Plan, the role of the JSC (such role outlined below at Article 3), and as otherwise outlined in this Article 2, Momenta shall, with respect to each Product, undertake, and have the right to [**] with respect to:

(i) CMC Activities (including Process Engineering Activities) prior to GMP; provided, however, that Momenta shall seek, and consider in good faith, Baxter's comments with respect to the manufacture of a Product; and provided further, however, that Momenta shall not have the right to enter into any agreement with a Third Party with respect to the manufacture or supply of a Product without Baxter's prior written consent, which consent shall not be unreasonably withheld;

(ii) Characterization Activities;

(iii) the regulatory strategy pertaining to non-clinical demonstration of similarity and interchangeability;

(iv) prior to the initiation of clinical studies with respect to a Product, regulatory meetings and communications with the applicable Regulatory Authority. Such rights outlined in this subsection (iv) are subject to Section 2.6 below; and

(v) all other non-Clinical Development Activities (including Quality Management Systems if Momenta conducts cGMP manufacturing activities either itself or through a Third Party) occurring prior to achievement of IND Acceptance of the Product.

(d) Baxter Responsibilities. In general, subject to the applicable Product Work Plan, the role of the JSC, and as otherwise outlined in this Article 2, Baxter shall, with respect to each Product, undertake, and have the right to [**] with respect to:

(i) revising and/or modifying the Clinical Development strategy following IND Acceptance; provided, however, that Baxter shall use good faith efforts, acting through the JSC, to achieve consensus on such strategy and if such consensus is not reached, the Parties shall undertake an abbreviated dispute resolution process as set forth in Section 12.11;

(ii) execution of the then-current Clinical Development strategy;

(iii) GMP manufacturing and supply of the Products, including identification and engagement of a contract manufacturer, which may include engaging Baxter. Notwithstanding the foregoing, Baxter shall use good faith efforts to provide Momenta with the opportunity to review and comment on any draft agreements with a potential contract manufacturer;

(iv) following the initiation of clinical studies with respect to a Product, all regulatory filings, meetings and communications with the applicable Regulatory Authority (including the Clinical Development obligations of the Parties in relation to a Product to obtain Regulatory Approval of such Product, as such is determined by communications with Regulatory Authorities). The rights outlined in this subsection (iv) are subject to Section 2.6 below;

(v) all Commercialization Activities; and

(vi) following IND Acceptance in the applicable country in the Territory, all matters related to such Product.

(e) Joint Responsibilities. Subject to the applicable Product Work Plan, the role of the JSC, and as otherwise outlined in this Article 2, the Parties shall, with respect to each Product, [**] and be responsible for:

(i) developing the Clinical Development strategy prior to IND Acceptance;

(ii) Product registration and regulatory strategy (including joint preparation and review of related regulatory applications and briefing books);

(iii) preparation of the formal IND submission (or foreign equivalent), as required, (which shall be submitted in the name of one or both Parties, as allowed for under applicable Law, provided that the IND shall be, as applicable, amended prior to the commencement of clinical trials to reflect only Baxter's name);

(iv) developing, reviewing and amending, if necessary, the Technical De-Risking Criteria for each Product with respect to items 1.a. and 3. of Exhibit 1.89; provided, however, that for the first Initial Product (also referred to herein as [**]) the Parties agree that the values for items 1.a. and 3. shall be [**] and [**] respectively. For all other Products, the Technical De-Risking Criteria for such items shall be established by the JSC within [**] of the [**], or in the case of the second Initial Product (also referred to herein as [**]) within [**] of the [**] of this Agreement;

(v) following [**] of a Product, CMC Activities (including quality) with respect to GMP manufacturing; and

(vi) legal strategy for the Legal Activities (this subparagraph (vi) is subject to, and does not modify the explicit allocation of the roles, rights and responsibilities provided for in Article 5).

2.5 Limitation on [**]. Notwithstanding the provisions of Sections 2.4(c) and 2.4(d), neither Party shall [**] its [**] to [**] a [**] pursuant to Sections 2.4(c) and 2.4(d), as applicable, to the extent it would require the other Party to [**].

2.6 Regulatory Matters. Notwithstanding the rights and responsibilities outlined at Sections 2.4(c) and 2.4(d) above, each Party shall have the opportunity to review and comment on all substantive communications in advance of any formal meeting with Regulatory Authorities and appropriate individuals from both Parties, as approved by the JSC, will be invited as meeting participants to any meetings with the relevant Regulatory Authorities.

2.7 Commercialization.

(a) Generally. Baxter shall use Commercially Reasonable Efforts to Commercialize each Product within [**] following receipt of Regulatory Approval for the applicable Product in [**]. Baxter shall Commercialize each Product in [**].

(b) Conversion to Non-Exclusive License. If, following notice from Momenta that Baxter is in breach of its obligations pursuant to Section 2.7(a) with respect to a specific Product and a specific country included in the Major Countries, Baxter fails to cure such breach pursuant to the terms of Section 10.4 (each such Major Country, a “Breached Country”), then, notwithstanding the provisions of Section 10.4, Momenta shall not have the right to terminate this Agreement but rather each of the licenses granted to Baxter pursuant to Section 6.1 with respect to such Product in such Breached Country shall no longer be an exclusive license but shall, instead, be amended, with no further action required by either Party, to reflect a non-exclusive license and Momenta shall thereafter be entitled to directly commercialize the Product itself in the applicable Breached Country. For the avoidance of doubt, the licenses shall be converted on a Product-by-Product, country-by-country basis only with respect to those Products and those countries in which Baxter has breached its obligations and failed to cure such breach pursuant to the terms of this Agreement.

In the event a license granted to Baxter with respect to a Product is converted to a non-exclusive license in a Breached Country as contemplated above, the Parties shall take such action as is reasonably necessary to supply Momenta with access to such Product for distribution or sale in such Breached Country. Recognizing that the form of arrangement will vary due to the legal requirements for appointing a distributor or the holding of a Regulatory Approval, the Parties will discuss in good faith, taking into consideration, *inter alia*, the Major Country in question, the regulatory scheme, the fact that Baxter will also retain the right to Commercialize the Product in such country, and the actions Baxter can reasonably take to put Momenta in a position to effectively act as an non-exclusive authorized distributor. Such actions may include, but shall not be limited to: (i) the granting to Momenta of a reference right for the applicable Regulatory Approvals in such country and (ii) the sale to Momenta of the applicable Product at a transfer price equal to actual Cost of Goods Sold for such product [**].

(c) Termination. Notwithstanding the restriction on termination of this Agreement set forth in Section 2.7(b), if: (i) the U.S. is a Breached Country with respect to a Product or (ii) (a) there are [**] or more Breached Countries with respect the applicable Product and (b) the projected annual gross sales for the applicable Product for all Breached Countries (as set forth in the Commercialization Plan) exceeds [**] percent ([**]%) of the projected annual gross sales of such Product for all Major Countries in the Territory, Momenta shall have the right to terminate this Agreement in the entire Territory by providing written notice to Baxter; provided, however, that such termination shall be effective solely with respect to such Product.

2.8 Technology Transfer Costs. Notwithstanding any other provision of this Agreement to the contrary, the Parties agree that all costs and expenses related to Technology Transfer to a contract manufacturing organization (including Baxter in the event Baxter is the contract manufacturing organization) that performs the pilot scale manufacturing process (the

“ Pilot Scale CMO ”) shall be borne [**] and all costs for Technology Transfer from a Pilot Scale CMO [**] or [**] for the commercial manufacture of the applicable Product shall be borne [**].

ARTICLE 3. GOVERNANCE

It is the intent of the Parties that, subject to Article 2 above, the Development and Commercialization Activities and associated Legal Activities and decisions for each Product be conducted and managed on an on-going basis through the Joint Steering Committee, and any relevant Sub-Committees or working groups using Commercially Reasonable Efforts.

3.1 Generally. The Parties will establish a joint steering committee (“ Joint Steering Committee ” or “ JSC ”) composed of senior members from each Party to oversee and manage the Development and Commercialization of a Product. The structure, scope of responsibility and authority of the JSC shall be as set forth in this Article 3.

3.2 Structure. The JSC shall consist of three (3) representatives from each of Baxter and Momenta. The JSC shall appoint a chairperson from among its members, which shall initially be a representative from Momenta, and then rotate annually between the Parties. The chairperson shall be responsible for calling meetings of the JSC and for leading the meetings. The initial JSC representatives for each Party shall be set forth in writing within [**] after the Effective Date. Each Party may replace its representatives by providing written notice to the other Party. Employees and other representatives of each Party that are not members of the JSC may attend meetings of the JSC and any Sub-Committees (as defined below) as required to further the activities contemplated by this Agreement.

3.3 Time and Location of Meetings. The JSC (and all Sub-Committees thereof) shall meet at such times and places, in person or by telephone conferencing, web-conferencing, video conferencing or other electronic communication, as the JSC shall determine to carry out its responsibilities; provided, however, that the initial meeting of the JSC shall be held in person at such location as mutually agreed upon by the Parties no later than [**] after the Effective Date. Thereafter, the JSC shall meet in person at least [**] times each calendar year and shall hold regular teleconferences between meetings not less frequently than [**]. The location of the in-person meetings shall alternate between the sites of the two Parties. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate to attend such meeting in place of the absent representative.

3.4 Minutes. The JSC and all Sub-Committees thereof shall designate for each meeting one person who shall be responsible for drafting and issuing minutes of the meeting reflecting all material items discussed and any agreements of the JSC, which minutes shall be distributed to all JSC members for review and approval. Such minutes shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JSC. Minutes of each JSC meeting shall be approved or disapproved, and revised as necessary, within [**] of each such meeting. Final minutes of each meeting shall be distributed to the members of the JSC by the chairperson.

3.5 Sub-Committees. At its initial meeting the JSC shall agree upon the formation of certain sub-committees (each a “Sub-Committee”), each with an equal number of representatives from Baxter and Momenta to address specific issues in greater detail. Unless otherwise agreed and except with respect to those matters addressed in Sections 2.4(c) and 2.4(d), [**] on all Sub-Committees. At its initial meeting, the JSC shall establish and appoint members to the Sub-Committees and each such Sub-Committee shall hold its first meeting in person within [**] of its formation at such location designated by the JSC.

3.6 Scope of Authority; Responsibilities.

(a) The JSC shall, subject to the restrictions set forth in this Agreement, have the authority to make decisions relating to the ongoing management of the relationship between the Parties with respect to this Agreement. The JSC shall have such other responsibilities as set forth herein and as the Parties may agree in writing from time to time.

(b) For the avoidance of doubt, the JSC shall have no authority to: (A) amend any of the terms of this Agreement; (B) waive any rights that either Party may otherwise have pursuant to this Agreement or otherwise; or (C) allocate the ownership of any Patent Rights or rights to any Know-How or the Parties’ rights to apply for Patent(s). Notwithstanding the foregoing, the JSC may make recommendations to the Parties for amendment of this Agreement.

3.7 Decisions; Disputes.

(a) Except as expressly set forth above in Sections 2.4(c) and 2.4(d) with respect to certain decisions of the Parties, the decisions of the JSC (including any Sub-Committee thereof) must be unanimous with representatives of Baxter having one collective vote and representatives of Momenta having one collective vote.

(b) If a dispute arises regarding matters within the scope of responsibilities of the JSC, and the JSC fails to reach a unanimous decision on its resolution within [**] of when the dispute was first presented to the JSC, then the matter shall be elevated through each Party’s respective senior management representatives pursuant to Section 12.11 and Exhibit 12.11.

3.8 Costs and Expenses. Each Party shall be responsible for all travel costs and out-of-pocket expenses incurred by its respective representatives in connection with attending the meetings and otherwise being part of the JSC and of the Sub-Committees. For the avoidance of doubt, travel time to and from meetings or other related travel shall not be counted as part of FTE time.

3.9 Term of the JSC and Sub-Committees. The JSC and each Sub-Committee, as applicable, shall, unless otherwise mutually agreed by the Parties, continue with respect to each Product through the Term of the Agreement. Following the [**] anniversary of the First Commercial Sale of the applicable Product, Momenta shall have the right but not the obligation to participate in the JSC and Sub-Committees that are then-operating in support of such Product.

ARTICLE 4.
FINANCIAL TERMS

4.1 Payments.

- (a) Up-Front Payment. Upon the later of (i) ten (10) days after the Effective Date of the Agreement, or (ii) January 19, 2012, Baxter shall make a one-time payment to Momenta of Thirty Three Million Dollars (USD\$33,000,000).
- (b) Extension of Naming Period. For each Naming Period extension requested, Baxter shall pay to Momenta the amount set forth at Section 2.2(c)(ii).
- (c) Option Payment. For each Product Option exercised, Baxter shall pay to Momenta the Option Payment set forth at Section 2.2(d).

4.2 Development Expenses and Commercialization Costs. Unless Momenta exercises its option to enter into the Cost/Profit Share arrangement pursuant to Section 4.10 (in which case the terms set forth in Section 4.10 shall apply) the following shall apply:

(a) Development Expenses. Prior to achievement of the IND Acceptance, Momenta shall be responsible for Development Expenses related to the applicable Product, except for clinical (human) studies and GMP manufacturing activities intended to support Clinical Development.

(i) In the event Baxter: (A) fails to proceed with such GMP manufacturing activities, (B) fails to pay for contracts associated with such GMP manufacturing activities, or (C) fails to commit in writing to reimburse Momenta (per below) in relation to a specific Product, for GMP manufacturing activities which are to be conducted prior to IND Acceptance for such Product, Momenta shall have the option, but not the obligation, to proceed with such GMP manufacturing activities in relation to the applicable Product and to charge to Baxter, following IND Acceptance for such Product, [**] percent ([**]%) of Momenta's Development Expenses incurred for such GMP manufacturing activities. Baxter shall provide notice to Momenta of the decision not to proceed with such GMP manufacturing activities at least [**] prior to the planned initiation of such GMP manufacturing activities as such is specified in the applicable Product Work Plan or applicable manufacturing contract(s).

(ii) If, following IND Acceptance of a Product, Baxter: (A) fails to proceed with clinical (human) studies, (B) fails to pay for contracts associated with such clinical (human) studies, or (C) fails to commit in writing to reimburse Momenta (per below) in relation to a specific Product, for such clinical (human) studies, Momenta shall have the option, but not the obligation, to proceed with such clinical (human) studies in relation to the applicable Product and to charge to Baxter, [**] percent ([**]%) of Momenta's Development Expenses incurred for such clinical (human) studies. Baxter shall provide notice to Momenta of the decision not to proceed with such clinical (human) studies activities at least [**]

prior to the planned initiation of such clinical (human) studies as such is specified in the applicable Product Work Plan or applicable clinical contract(s).

(iii) [**] of an applicable Product, if achievement of the [**] has not yet occurred, Baxter shall be responsible for [**] percent ([**]%) of Development Expenses incurred by Momenta [**] of such Product and [**]%) of Development Expenses incurred by Baxter, [**] of such Product, except with respect to clinical (human) studies and GMP manufacturing activities intended to support Clinical Development, for which Baxter will be [**] percent ([**]%) responsible. All Development Expenses of the Parties are to be incurred in accordance with the applicable Product Work Plan.

(iv) Following achievement of both: (A) [**] and (B) [**] with respect to the applicable Product, Baxter shall be responsible for [**] percent ([**]%) of all Development Expenses associated with such Product incurred after achievement of both such events, unless Momenta has elected a Cost/Profit Share arrangement as provided for in Section 4.7 below, in which case Momenta shall be responsible for the selected Cost Share related to the Additional Products.

(v) The [**] will have been determined to have been achieved upon the earlier of: (A) objective achievement the [**]; (B) JSC determination that the [**]; or (C) if [**] elects, [**], that it will proceed with the next stage (*e.g.* [**].) of Development of the Product.

(b) Commercialization Costs. Baxter shall be responsible for one hundred percent (100%) of all Commercialization Costs associated with the Products, except where Momenta has elected a Cost/Profit Share arrangement as provided for in Section 4.7 below, in which case Momenta shall be responsible for the selected Cost Share related to the Additional Products.

4.3 Legal Expenses. Article 5, below, sets forth the rights and responsibilities of the Parties, including the financial rights and obligations of the Parties, with respect to the Legal Activities.

4.4 Third Party Payments.

(a) Disclosure. Momenta has disclosed to Baxter, prior to the Execution Date, all contracts and agreements (whether written or oral) that could, to Momenta's knowledge as of the Execution Date, result in Third Party Payments (including, without limitation license fees, annual payments, and royalties) for licensed Third Party Patent Rights and/or Know-How with respect to the Commercialization of the Initial Products. Baxter has disclosed to Momenta, prior to the Execution Date, all contracts and agreements (whether written or oral) that could, to Baxter's knowledge as of the Execution Date, result in Third Party Payments (including, without limitation license fees, annual payments and royalties) for licensed Third Party Patent Rights and/or Know-How with respect to the Commercialization of the Initial Products.

(b) Reimbursable Third Party Payments: Neither Party shall, to its knowledge, enter into an agreement with a Third Party for licensed Third Party Patent Rights and/or Know-How with respect to the right to Develop or Commercialize the Product that would result in Third Party Payments (including without limitation, license fees, annual payments and royalties), without (i) prior written notice to the other Party, and (ii) the consent of the JSC, which consent shall not be unreasonably withheld. Upon the approval of the JSC of such an agreement, the Parties shall be responsible for, and allocate by Allocable Legal Expense Share, the Third Party Payments (including, without limitation license fees, annual payments and royalties) due for licensed Third Party Patent Rights and Know-How that are related to or are Product-specific (referred to as “Reimbursable Third Party Payments”). Baxter shall have the right to treat Third Party Payments for Third Party Patent Rights and/or Know How related to commercial manufacturing, testing, releasing, packaging and/or labeling as part of Cost of Goods Sold; provided that with respect to Products which are subject to a Cost/Profit Share under Section 4.7, reimbursement of such Third Party Payments shall not be made under this Section 4.4(b) and shall be made in connection with the Profit Share Percentage and payments under Section 4.7.

(c) Third Party Payments: The Parties’ responsibilities with respect to certain other Third Party Payments shall be as follows:

(i) Momenta shall be *** for and shall pay *** percent (***%) of the Third Party Payments (including, without limitation license fees, annual payments and royalties) due for licensed Third Party Patent Rights and Know-How that are not *** to one or more Products and which are used by Momenta *** in Development of a Product (e.g. Third Party Patent Rights and/or Know-How with respect to a *** or ***).

(ii) Baxter shall be *** for and shall pay *** percent (***%) of the Third Party Payments (including, without limitation license fees, annual payments and royalties) due for licensed Third Party Patent Rights and Know-How that are used in the Commercialization of a Product but only to the extent such Third Party Patent Rights and Know-How are not *** for the Commercialization of a Product (e.g. Third Party Patent Rights and/or Know-How related to the *** of a Product (e.g. , a ***)).

(d) *** to be paid to Momenta.

4.5 Milestone Payments. Baxter shall pay to Momenta, in each case subject to the successful achievement of each objective described below, with respect to each Initial Product or Additional Product (as noted below):

(a) *** Dollars (USD\$***) upon achievement of the *** for the Initial Product known as ***;

(b) *** Dollars (USD\$***) upon *** for each Initial Product;

(c) [**] Dollars (USD\$[**]) upon [**] for [**] if the [**] occurs on or prior to [**] (this milestone is [**] for such Initial Product at Section 4.5(b) above);

(d) [**] Dollars (USD\$[**]) upon [**] if the [**] occurs on or prior to [**]; (this milestone is [**] for such Initial Product at Section 4.5(b) above);

(e) [**] Dollars (USD\$[**]) upon the later to occur of (i) [**] for the applicable Initial Product or (ii) achievement of [**] for each applicable Initial Product;

(f) [**] Dollars (USD\$[**]) upon [**] for each applicable Additional Product;

(g) [**] Dollars (USD\$[**]) upon the later to occur of (a) [**] for the applicable Additional Product or (b) [**] for each applicable Additional Product; and

(h) [**] Dollars (USD\$[**]) for the applicable Product in either the [**], provided that a [**]; provided, however that if the [**]:

(i) exceed [**] Dollars (USD\$[**]) but are less than [**] Dollars (USD\$[**]) and

(ii) exceed [**] Dollars (USD\$[**]).

4.6 Royalty Payments. Baxter shall pay to Momenta a royalty of up to [**] percent ([**]%) of annual Net Sales of the applicable Product (regardless of the regulatory pathway or law under which the applicable Product was approved) as follows:

(a) [**] percent ([**]%) of annual Net Sales of the applicable Product; plus

(b) Additional royalty of [**] percent ([**]%) of annual Net Sales of the applicable Product in excess of [**] Dollars (USD\$[**]) in the applicable calendar year.

In the [**] of an applicable calendar year in which year-to-date cumulative Net Sales exceed [**] Dollars (USD\$[**]) the allocated portion of quarterly Net Sales to which the [**]% royalty rate shall be applied shall be determined as follows: [**] Dollars (USD\$[**]) minus cumulative annual Net Sales of the Product through the [**] that cumulative annual Net Sales of the Product exceeds [**] Dollars (USD\$[**]) / cumulative annual Net Sales of the Product [**] that cumulative annual Net Sales of the Product exceeds [**] Dollars (USD\$[**]) minus the cumulative annual Net Sales of the Product through [**] that cumulative Net Sales of the Product exceeds [**] Dollars (USD\$[**]) (the “Allocation Fraction”).

In the [**] in which cumulative annual Net Sales are greater than [**] Dollars (USD\$[**]) the allocated portion of quarterly Net Sales to which the [**]% royalty rate shall be applied shall be determined as follows: ([**]) multiplied by such [**]; plus

30

(c) Additional royalty of [**] percent ([**]%) of annual Net Sales, if the applicable Product is the Sole Interchangeable Product in the applicable country in the Territory (for purposes of this Section 4.6, in the case of the EU, Territory shall refer to the individual nations in the EU); plus

(d) Additional royalty of one of the following based upon the number of Competing Products then being sold in the relevant country in the Territory by a Third Party:

Number of Competing Products in the applicable country in the Territory	Additional Royalty
0	[**] Percent ([**]%) of annual Net Sales
1	[**] Percent ([**]%) of annual Net Sales
2	[**] Percent ([**]%) of annual Net Sales
3+	[**]

Changes to the royalty rate based on the number of Competing Products in the applicable country in the Territory as outlined this Section 4.6(d) shall take effect on the first day of the calendar quarter following the Launch or discontinuation (e.g. no longer offered for sale) of such Competing Product in such country of the Territory.

4.7 Profit Share. Momenta will have a one-time option to opt-into an arrangement whereby Baxter and Momenta share the costs and profits related to all of the Additional Products (“Cost/Profit Share”) as further detailed below. Such option shall be exercisable, at Momenta’s sole discretion, within [**] following Momenta’s receipt of the [**] (the “Profit Share Election Period”):

(a) Prior to the expiration of the Profit Share Election Period, Momenta shall have the right to provide written notice to

Baxter (the “ Profit Share Election Notice ”) of its election to opt-into a Cost/Profit Share arrangement.

(b) Momenta shall have the right to elect a Cost/Profit Share of either (a) [**] percent ([**]%), (b) [**] percent ([**]%), or (c) thirty percent (30%) (as applicable, the “ Profit Share Percentage ”). Following Momenta’s delivery of the Profit Share Election Notice to Baxter, Momenta shall be responsible for the elected Cost/Profit Share. The Parties agree that ‘Profits’ may be negative (*i.e.* there may be a loss) depending on the timing of the election and the success of the Product.

(c) Upon delivery of the Profit Share Election Notice to Baxter with respect to the first Additional Product, the Profit Share Percentage selected shall also apply to all other Additional Products for which Baxter provides an Exercise Notice.

(d) Upon Momenta’s delivery to Baxter of the Election Notice, the royalties otherwise payable by Baxter to Momenta under this Agreement as set forth in Section 4.6 shall be subject to reduction as outlined in the table below (such reduction the “Royalty Offset”):

Profit Share Percentage Election	Royalty Offset (% reduction of Royalties otherwise payable by Baxter)	
	[**]%	[**]%
	[**]%	[**]%
	30%	[**]%

(For avoidance of doubt, Exhibit 4.7 contains several examples of the operation of the royalty, milestone and Cost/Profit Share provisions under several Commercialization scenarios).

4.8 Books and Records. During the Term of this Agreement, the Parties shall keep, and shall ensure that their respective Affiliates and sublicensees shall keep, complete and accurate records in sufficient detail to make the reports required hereunder, to confirm compliance with the provisions of this Agreement, to properly reflect all amounts billed, owed or reported and to verify the amounts payable hereunder for a period of three (3) years after such payments are made.

4.9 Reports.

(a) Cost/Profit Share Reports. Baxter shall deliver to Momenta within [**] days after the last day of each calendar quarter in which the applicable Product is sold a good faith estimate and within [**] days after the last day of each calendar quarter in which the applicable Product is sold, a final report setting forth:

(i) the gross sales of all Products on a Product-by-Product and country-by-country basis, sold by Baxter, its Affiliates and sublicensees during the calendar quarter and the calculation of Net Sales of the Products from gross sales;

(ii) the amount of any Sublicense Revenue received by Baxter during the calendar quarter, if relevant;

(iii) the calculation of the Profits, including detailed information on the Cost of Goods Sold and Marketing and Selling Expenses, from which the Profits are determined. If no Profit Share is due, the report shall so state.

(b) Royalty Reports. Baxter shall deliver to Momenta [**] days after the last day of each calendar quarter in which the applicable Product is sold a good faith estimate and within [**] days after the last day of each calendar quarter in which the applicable Product is sold, a final report, a report setting forth:

(i) the gross sales of all Products on a Product-by-Product and country-by-country basis, sold by Baxter, its Affiliates and sublicensees during the calendar quarter and the calculation of Net Sales of the Products from gross sales;

(ii) the amount of any Sublicense Revenue received by Baxter during the calendar quarter, if relevant;

(iii) the calculation of the royalties, including detailed information on the royalty rates, from which the royalties are determined. If no royalty is due, the report shall so state.

(c) Momenta Reporting. To the extent that Momenta obtains the right to Commercialize a Product as a result of Baxter's breach of Section 2.7, Momenta shall have the same reporting obligations as Baxter under Sections 4.9(a) and 4.9(b) and all references to Baxter therein shall be replaced with Momenta and all references to Momenta shall be replaced with Baxter.

(d) Legal Expense Reports. Each Party shall deliver to the other Party within ten (10) business days after the last day of each calendar quarter, a report of the Legal Expenses incurred in such calendar quarter that are allocated under the Agreement between the Parties, along with a calculation of the amount allocable to each Party.

(e) Reimbursable Third Party Payment Reports. Each Party shall deliver to the other Party within [**] days after the last day of each calendar quarter, a report of the Reimbursable Third Party Payments that are allocated under the Agreement between the Parties, along with a calculation of the amount allocable to each Party.

4.10 Cost Share Reports and Payments of Cost Share, Profit Share, the Up Front Payment, Royalties and Milestones. If Momenta exercises its option to enter into the Cost/Profit Share arrangement the following shall apply:

(a) Prior to IND Acceptance — Development Expenses. Prior to IND Acceptance, Baxter shall invoice Momenta quarterly for Development Expenses incurred by Baxter in accordance with the applicable Product Work Plan, promptly following the end of each calendar quarter.

(b) [**] and Prior to [**] — Development Expenses. [**] and prior to [**], Momenta and Baxter shall each report to the other the Development Expenses incurred by each Party in accordance with the applicable Product Work Plan and authorized by the JSC (in the case of Momenta, such Development Expenses shall mean those expenses incurred by Momenta in conduct of the Development Activities [**]). The Party which incurs Development Expenses in excess of the other Party shall invoice such other Party for [**] percent ([**]%) of such excess promptly following the end of each calendar quarter.

(c) Following IND Acceptance and [**] — Development Expenses. Following both IND Acceptance and [**], Momenta shall invoice Baxter quarterly for Development

Expenses incurred by Momenta in accordance with the applicable Product Work Plan and authorized by JSC, promptly following the end of each calendar quarter.

(d) Commercialization Costs. Momenta shall invoice Baxter quarterly for all Commercialization Costs incurred by Momenta as authorized by the JSC, promptly following the end of each calendar quarter.

(e) Legal Expenses and Reimbursable Third Party Expenses. The Parties shall total each Party's Allocable Legal Expense Share of the Legal Expenses and Reimbursable Third Party Payments reported under 4.9(c) and (e) within [**] days of the end of the last day of the calendar quarter. The net amount owing to a Party shall be promptly invoiced by the Party to whom it is owed to the other Party.

(f) Timing of Payments. Unless otherwise provided herein, (i) Development Expenses, Commercialization Costs, Legal Expenses, and Reimbursable Third Party Expenses shall be paid within [**] days of invoice, (ii) all royalties due to Momenta or Baxter under this Agreement shall be paid within [**] days of the end of the calendar quarter during which the applicable Net Sales were made, and (iii) if applicable, the Profit Share due to Momenta under this Agreement shall be paid within [**] days after the last day of the calendar quarter in which the Profits accrue. All amounts shall be paid in U.S. Dollars. To the extent royalties or Profits on any sales are made outside the U.S., the amounts payable to Momenta or Baxter for such sales shall be determined based upon the paying Party's normal foreign currency conversion practices throughout the applicable quarter.

(g) Overdue Payments. In the event the upfront payment, any milestone payment, royalty payment, Option Payment, Cost Share or Profit Share payment, or other such payment owed by Baxter to Momenta, or Cost Share payment or such other payment owed by Momenta to Baxter, under this Agreement is not made when due, such outstanding payment shall constitute a material breach of this Agreement and shall accrue interest (from the date such payment is due through and including the date upon which full payment is made) at a rate of one half of one percent (0.5%) per month from the due date until paid in full, provided that in no event shall said annual rate exceed the maximum interest rate permitted by law in regard to such payments. Such payment, when made, shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate nor waive the right of Momenta or Baxter to any other remedy, legal or equitable, to which it is entitled because of the delinquency of the payment.

4.11 Taxes. All amounts due to either Party hereunder shall not be reduced by any value-added tax or any other sales tax or duties; provided, however, that the Parties shall cooperate to minimize any tax liability; provided however, that the payor shall deduct any applicable withholding taxes or similar mandatory governmental charges levied by any governmental jurisdiction from the amount due to the other party hereunder. Baxter and Momenta will cooperate in obtaining any necessary documentation required under applicable tax law, regulation, or intergovernmental agreement.

4.12 Audits; Records and Inspection. Baxter and Momenta shall keep, and cause its Affiliates and sublicensees to keep, complete, true and accurate books of account and records for the purpose of determining the Development Expenses, Commercialization Costs, Reimbursable Third Party Payments, Legal Expenses, royalty, and, as applicable, the Profit Share, amounts payable to Momenta or Baxter, as applicable, under this Agreement. Such books and records shall be kept at the principal place of business of Baxter or its Affiliates or authorized sublicensees, or Momenta or its Affiliates, as the case may be, for at least [**] years following the end of the calendar quarter to which they pertain. Upon [**] days prior written notice from a Party, the other Party shall permit, and shall ensure that its Affiliates and sublicensees shall permit, an independent certified public accounting firm of recognized national standing in the U.S., selected by the requesting Party and reasonably acceptable to the other Party, at the requesting Party's expense, to have access to such Party's (or their Affiliates or sublicensees) records, specific to a country in a Territory as appropriate, as may be reasonably necessary to verify the accuracy of any amounts reported, actually paid or payable under this Agreement for any year ending not more than [**] prior to the date of such request. Such audits may be made no more than once each calendar year, during normal business hours at reasonable times mutually agreed by the Parties. If such accounting firm concludes that additional amounts were owed to the requesting Party during such period with respect to such country of the Territory as applicable, or if the requesting Party overpaid for any rates or fees for products or services with respect to such country of the Territory, the other Party shall pay such additional amounts or refund such overpayment (including interest on such additional sums with respect to such country of the Territory in accordance with Section 4.10(g)) within [**] days of the date the requesting Party delivers to the other Party such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by the requesting Party; provided, however, that if the audit discloses that the amounts payable to such Party for the audited period are more than [**] percent ([**]%) of the amounts actually paid for such period in such country of the Territory as applicable, or if the audit discloses that the other Party has overcharged the requesting Party for rates or fees for products or services period in such country of the Territory as applicable, by over [**] percent ([**]%), then the other Party shall pay the reasonable fees and expenses charged by such accounting firm. Upon the expiration of [**] following the end of any calendar year, the calculation of any amounts payable with respect to such calendar year, or rates or fees charged for such year shall be binding and conclusive upon the Parties.

ARTICLE 5. INTELLECTUAL PROPERTY AND LITIGATION

5.1 Ownership of Intellectual Property. Baxter shall own and retain all right, title, interest and ownership in Baxter Intellectual Property, including that developed prior to the Effective Date and that developed independently outside the course of the Collaboration. Momenta shall own and retain all right, title, interest and ownership in the Momenta Intellectual Property, including that developed prior to the Effective Date and that developed independently outside the course of the Collaboration. The Parties shall jointly own all Collaboration Intellectual Property developed in the course of the Collaboration. For the avoidance of doubt, the Collaboration commences with the Effective Date with respect to the Initial Products and upon the exercise of the Product Option with respect to the Additional Products.

5.2 Improvements. Baxter shall own all right, title, interest and ownership in and to Baxter Improvements created in the course of the Collaboration. To the extent such Baxter Improvements are developed by Momenta and/or its Affiliates and/or their respective employees, contractors or consultants, Momenta hereby assigns to Baxter all right, title and interest in and to such Baxter Improvements, and all intellectual property rights therein. Momenta shall own all right, title, interest and ownership in and to the Momenta Improvements created in the course of the Collaboration. To the extent such Momenta Improvements are developed by Baxter and/or its Affiliates and/or their respective employees, contractors or consultants, Baxter hereby assigns to Momenta all right, title and interest in and to such Momenta Improvements, and all intellectual property rights therein.

5.3 Prosecution and Maintenance of Patent Rights.

(a) Generally. Baxter shall have the right and responsibility, in its sole discretion, to prepare, file, prosecute and maintain patent protection with respect to the Baxter Patent Rights. Momenta shall have the right and responsibility, in its sole discretion, to prepare, file, prosecute and maintain patent protection with respect to the Momenta Patent Rights. The Parties shall have the joint right and responsibility to prepare, file, prosecute and maintain patent protection with respect to Collaboration Patent Rights in the names of both Parties. Patent counsel from the Parties shall jointly review and agree on the appropriate course of action and control with respect to the preparation, filing, prosecution and maintenance of the Collaboration Patent Rights.

(b) Cooperation. Each Party shall make available to the Party filing, prosecuting or maintaining any Collaboration Patent Rights, or such Party's authorized attorneys, agents or representatives, such of its employees whom such controlling Party in its reasonable judgment deems necessary in order to assist it in obtaining patent protection for such Collaboration Patent Rights.

(c) Responsibility for Legal Expenses. Responsibility for Legal Expenses associated with patent prosecution and maintenance shall be as follows:

(i) Momenta Patent Rights/Baxter Patent Rights. Momenta shall be responsible for and shall pay all Legal Expenses associated with the protection of and related preparation, filing, prosecution and maintenance of the Patent Rights within the Momenta Intellectual Property. Baxter shall be responsible for the protection of and shall pay all Legal Expenses associated with the protection of and related preparation, filing, prosecution and maintenance of the Patent Rights within the Baxter Intellectual Property.

(ii) Collaboration Patent Rights. Prior to IND Acceptance, Momenta shall be responsible for and shall pay all expenses associated with the preparation, filing, prosecution and maintenance of the Collaboration Patent Rights within the Collaboration Intellectual Property during that time. Upon IND Acceptance, each Party shall be responsible for [**] percent ([**]%) of the Legal Expenses associated with the preparation, filing, prosecution and maintenance of the Collaboration Patent Rights within the Collaboration Intellectual Property

following IND Acceptance. Following achievement of both IND Acceptance and [**] for a Product, Baxter shall be responsible for one hundred percent (100%) of the Legal Expenses associated with the preparation, filing, prosecution and maintenance of Collaboration Patent Rights within the Collaboration Intellectual Property for that Product.

5.4 Patent Enforcement/Third Party Infringement.

(a) Notice. Each Party shall promptly report to the other Party during the Term any known or suspected infringement or unauthorized use of any of the Baxter Intellectual Property, the Momenta Intellectual Property or the Collaboration Intellectual Property, licensed pursuant to Sections 6.1, 6.2(c) or 6.3, as the case may be, of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such known or suspected infringement or unauthorized use.

(b) Initial Meeting. Promptly following notification to the other Party of any known or suspected infringement or unauthorized use of any of the Baxter Intellectual Property, the Momenta Intellectual Property or Collaboration Intellectual Property, the JSC shall meet and shall (i) evaluate the notice of infringement and attempt to agree on the appropriate course of action and control with respect to enforcement proceedings and (ii) determine which Party or Parties shall initiate the enforcement action. As part of the process of determining whether to pursue any Enforcement Litigation matter (as hereinafter defined), the JSC shall also decide whether or not to seek injunctive relief and/or post a bond in such Enforcement Litigation

(c) JSC-Approved Enforcement Litigation.

(i) If the Parties, acting through the JSC, agree to proceed with a patent enforcement or Third Party infringement litigation matter (including seeking injunctive relief and/or the posting of a bond) (the “Enforcement Litigation”) the JSC shall at such meeting discuss in good faith selection of the Party that will take the lead (the “Lead Party”) in managing such Enforcement Litigation. The Party that is not the Lead Party shall be referred to as the “Non-Lead Party”. Except as expressly set forth below or as otherwise agreed by the Parties, [**].

(ii) The Lead Party shall select counsel for the Enforcement Litigation and shall have the right to control the Enforcement Litigation, and the Non-Lead Party shall join the suit as a co-plaintiff. The Non-Lead Party shall have the right to participate in the Enforcement Litigation, and provide input directly to the Lead Party and Lead Party counsel. Lead Party counsel shall provide drafts of proposed court filings to the Non-Lead Party for review reasonably in advance of filing to facilitate comments, input and exchange of ideas unless exigent circumstances require immediate action. Input will be provided promptly to counsel.

(iii) The Parties and their counsel shall seek to agree on joint Enforcement Litigation strategy and pleadings recognizing the importance of alignment to the

Enforcement Litigation. Counsel to the Parties shall also consult regularly to discuss Enforcement Litigation plans and strategy and conduct Enforcement Litigation review meetings as needed, but no less frequently than monthly. The Lead Party shall give due consideration to the Non-Lead Party's recommendations and advice with regard to claims, arguments and strategy in the Enforcement Litigation; provided, however, that if the Parties are unable to reach agreement on a particular strategy or pleading, then either Party may immediately escalate the matter to the Parties' representatives (in the case of Baxter, to the President of BioScience and in the case of Momenta to its President) to resolve the matter. If the matter cannot be resolved in [**] (or such shorter time period as may be necessary to meet a court deadline), then the Lead Party shall have the right to proceed without reaching consensus, and the Non-Lead Party shall have the right not to join in the Lead Party's pleadings or arguments but shall continue to participate to the extent necessary to sustain jurisdiction and to allow the continued assertion of the Non-Lead Party's damage claim.

(iv) All Legal Expenses related to an Enforcement Litigation matter that is approved by the JSC with respect to a Product (including any bond expenses and liability associated with the grant of injunctive relief) and damages resulting from such Enforcement Litigation shall be allocated between the Parties in accordance with their respective Allocable Legal Expense Shares. Further, for the avoidance of doubt, once the JSC has determined that the Parties shall move forward with an Enforcement Litigation matter, a Party shall not have the right to thereafter dissent and become a Passive Party pursuant to Section 5.4(d).

(d) Non-JSC-Approved Enforcement Litigation.

(i) If the Parties are unable to reach consensus at the JSC on initiating an Enforcement Litigation matter within [**] (or a shorter period of time if the circumstances warrant immediate action) following notification to the other Party of any known or suspected infringement or unauthorized use of any of the Baxter Intellectual Property, the Momenta Intellectual Property or the Collaboration Intellectual Property, the Parties shall vote on the matter at the JSC, and if there is still no consensus, then the affirmative voting Party, if such Party has the sole ownership of the Patent Rights at issue or if the enforcement action involves Collaboration Patent Rights, shall have the sole right and option to determine whether or not to proceed with any Enforcement Litigation. If such party determines to proceed with the Enforcement Litigation, such Party (hereinafter the "Active Party") shall have the sole and exclusive right to select counsel for the Enforcement Litigation initiated by it pursuant to this Section 5.4(d). The Party that is not the Active Party shall be referred to herein as the "Passive Party".

(ii) In any Enforcement Litigation brought by the Active Party pursuant to Section 5.4(d), the Passive Party shall join in such action as a party at the Active Party's request in the event that an adverse party asserts, the court rules or other Laws provide, or the Active Party determines in good faith, that a court would lack jurisdiction based on the Passive Party's absence as a party in such

suit or the lack of participation by the Passive Party would materially prejudice the Enforcement Litigation; but control of such Enforcement Litigation shall remain with the Active Party.

(iii) All Legal Expenses related to an Enforcement Litigation matter that is *not* approved by the JSC with respect to a Product (including any bond expenses and liability associated with the grant of injunctive relief) and damages resulting from such Enforcement Litigation shall be allocated between the Parties as follows:

(1) The Active Party shall *initially* be responsible for and shall pay [**] percent ([**]%) of all Legal Expenses associated with such Enforcement Litigation and the Passive Party shall *initially* be responsible for and shall pay [**] percent ([**]%) of such Legal Expenses; provided, however, that the maximum aggregate Legal Expenses for which the Passive Party shall be *initially* be responsible with respect to any specific Product shall be equal to the Legal Expense Cap.

(2) If the Active Party is ultimately successful in pursuing the Enforcement Litigation Matter, all Legal Expenses for such Enforcement Litigation matter and all damages resulting from such Enforcement Litigation shall be allocated between the Parties in accordance with their respective Allocable Legal Expense Shares. [**] for which the [**] is liable pursuant to this Section 5.4(d)(iii)(2) [**] for which the [**] was liable under Section 5.4(d)(iii)(1) shall be paid to the [**] in [**] (with [**]) with the [**] being due within [**] following receipt by the Passive Party of written notice from the Active Party that it has received the final, unappealable court order in such Enforcement Litigation matter.

(3) For the avoidance of doubt, the intent of the Parties is that each Party shall [**], as expressly set forth above, of [**] (or “[**]”) in any Enforcement Litigation matter that is [**] subject to the following:

(A) If the Active Party [**] the intent is that the Active Party shall be responsible for [**] percent ([**]%) of the [**] Dollars (USD\$[**]) of Legal Expenses [**].

(B) If the Active Party [**] the intent is to ensure that all Legal Expenses are borne by the Parties [**].

(iv) Settlement. Neither Party may settle or consent to an adverse judgment with respect to a suit, including any settlement or judgment which affects the scope, validity or enforcement of the other Party’s Intellectual Property, without the express written consent of such other Party (such consent not to be unreasonably withheld). However, the Party bringing suit may settle or consent to an adverse judgment in any action described without obtaining consent from the other Party as long as any such settlement or consent judgment does not

impose a financial obligation upon the other Party, or limit the scope of or invalidate any intellectual property of the other Party.

5.5 Patent Clearance, Exchange and Defensive Litigation; Third Party Suits .

(a) Patent Clearance, Exchange and Litigation . Within [**] for each Product, the JSC shall task counsel with developing a Collaboration plan for freedom to operate. The plan shall take into consideration alternative development strategies, licensing strategies, patent clearance under the BPCI Act patent exchange and litigation process, and other options that optimize the success of the Product and launch timing. The JSC shall meet and attempt to agree at least [**] for Regulatory Approval of a Product as to the appropriate course of action with respect to the patent clearance, exchange or litigation proceedings that may arise under the BPCI Act with respect to each Product. The Parties acknowledge that the timing for response to the BPCI Act clearance and exchange is brief and that a lead party will need to be selected to optimize effectiveness for the patent exchange process.

(b) Third Party Suits . In addition, in the event that a Third Party shall otherwise make any claim or bring any suit or other proceeding against a Party, or any of its Affiliates, sublicensees, or customers, for infringement or misappropriation of any intellectual property rights with respect to the research, development, making, using selling, offering for sale, import or export of any Product, the Party that becomes aware of such claim, suit or other proceeding shall notify the other Party and the Parties shall promptly convene a meeting of the JSC. All litigation matters contemplated by this Section 5.5 are hereinafter referred to as “Other Collaboration Litigation”.

(i) The JSC shall consider any potential Other Collaboration Litigation as a regular agenda item in their meetings and with the intent of being prepared to act in sufficient time to allow the Parties to make a timely determination and respond to any such actions. In connection therewith, the JSC shall discuss in good faith the coordination of all Other Collaboration Litigation (including patent exchange activities and litigation defense) and whether one Party should take the lead in any particular activity or suit. The JSC shall also determine, if applicable, whether the Parties [**].

(ii) Each Party shall have the right to be represented by its own counsel in such Other Collaboration Litigation matters unless the Parties elect to engage counsel jointly. The Parties shall cooperate in good faith, coordinate their input to counsel, and share drafts of proposed court filings for review reasonably in advance of filing to facilitate comments, input and exchange of ideas unless exigent circumstances require immediate action. Input will be provided promptly to counsel. The Parties and their counsel shall seek to agree on joint strategy and pleadings recognizing the importance of alignment. Counsel to the Parties shall also consult regularly to discuss plans and strategy, and have review meetings as needed, but no less than [**] once the BPCI Act exchange process or other litigation commences. Each Party shall give due consideration to the other Party’s recommendations and advice with regard to claims, arguments and

strategy; however, if the Parties are unable to reach agreement on a particular strategy or pleading, then either Party may immediately escalate the matter to the Parties representatives (in the case of Baxter, to the President of BioScience, in the case of Momenta to its President) to resolve the matter. If the matter cannot be resolved in [**] (or such shorter time period as may be necessary to meet a court deadline), then each Party shall have the right [**], and each Party shall have the right [**].

(c) JSC-Approved Other Collaboration Litigation .

(i) If the Parties, acting through the JSC, agree to proceed with an Other Collaboration Litigation matter, the JSC shall at such meeting discuss in good faith selection of the Party that will take the lead (the “Lead Party”) in managing such Other Collaboration Litigation. The Party that is not the Lead Party shall be referred to as the “Non-Lead Party”. Except as expressly set forth below or as otherwise agreed by the Parties, [**].

(ii) The Lead Party shall select counsel for the Other Collaboration Litigation and shall have the right to control the Other Collaboration Litigation, and the Non-Lead Party shall have the right to be represented by its own counsel. The Non-Lead Party shall have the right to participate in the Other Collaboration Litigation, and provide input directly to the Lead Party and Lead Party counsel. Lead Party counsel shall provide drafts of proposed court filings to the Non-Lead Party for review reasonably in advance of filing to facilitate comments, input and exchange of ideas unless exigent circumstances require immediate action. Input will be provided promptly to counsel.

(iii) The Parties and their counsel shall seek to agree on joint Other Collaboration Litigation strategy and pleadings recognizing the importance of alignment to the Other Collaboration Litigation. Counsel to the Parties shall also consult regularly to discuss Other Collaboration Litigation plans and strategy and conduct Other Collaboration Litigation review meetings as needed, but no less frequently than monthly. The Lead Party shall give due consideration to the Non-Lead Party’s recommendations and advice with regard to claims, arguments and strategy in the Other Collaboration Litigation; provided, however, that if the Parties are unable to reach agreement on a particular strategy or pleading, then either Party may immediately escalate the matter to the Parties’ representatives (in the case of Baxter, to the President of BioScience and in the case of Momenta to its President) to resolve the matter. If the matter cannot be resolved in [**] (or such shorter time period as may be necessary to meet a court deadline), then the Lead Party shall have the right to proceed without reaching consensus, and the Non-Lead Party shall have the right not to join in the other Lead Party’s pleadings or arguments and to assert its own

claims and defenses.

(iv) All Legal Expenses related to an Other Collaboration Litigation matter that is approved by the JSC with respect to a Product and damages resulting from such Other Collaboration Litigation shall be allocated between the

Parties in accordance with their respective Allocable Legal Expense Shares. Further, for the avoidance of doubt, once the JSC has determined that the Parties shall move forward with an Other Collaboration Litigation matter, a Party shall not have the right to thereafter dissent and become a Passive Party pursuant to Section 5.5(d); but a Non-Lead Party shall have the right to assert its own claims and defenses if the Lead Party does not elect to assert such claims and defenses on behalf of such Party.

(d) Non-JSC-Approved Other Collaboration Litigation.

(i) If the Parties are unable to reach consensus at the JSC on initiating an Other Collaboration Litigation matter, including the initiation of the patent exchange process under the BPCI Act, matter within [**] (or a shorter period of time if the circumstances warrant immediate action) following notification to the other Party of any known or suspected infringement or unauthorized use of any of the Baxter Intellectual Property, the Momenta Intellectual Property or Collaboration Intellectual Property, the Parties shall vote on the matter at the JSC, [**]. If such party determines to proceed with the Other Collaboration Litigation, such Party (hereinafter the “Active Party”) shall have the sole and exclusive right to select counsel for the Other Collaboration Litigation initiated by it pursuant to this Section 5.5(d). The Party that is not the Active Party shall be referred to herein as the “Passive Party”.

(ii) All Legal Expenses related to an Other Collaboration Litigation matter that is *not* approved by the JSC with respect to a Product (including any bond expenses and liability associated with the grant of injunctive relief) and damages resulting from such Other Collaboration Litigation shall be allocated between the Parties as follows:

(1) The Active Party shall *initially* be responsible for and shall pay [**] percent ([**]%) of all Legal Expenses associated with such Other Collaboration Litigation and the Passive Party shall *initially* be responsible for and shall pay [**] percent ([**]%) of such Legal Expenses; provided, however, that the maximum aggregate Legal Expenses for which the Passive Party shall be *initially* be responsible with respect to any specific Product shall be equal to the Legal Expense Cap.

(2) If the Active Party is [**], all Legal Expenses for such Other Collaboration Litigation matter and all damages resulting from such Other Collaboration Litigation shall be [**] for which the [**] is liable pursuant to this Section 5.5(d)(ii)(2) [**] for which the [**] was liable under Section 5.5(d)(ii)(1) shall be paid to the [**] in [**] (with [**]) with the [**] being due within [**] following receipt by the Passive Party of written notice from the Active Party that it has receive the final, unappealable court order in such Other Collaboration Litigation matter.

(3) For the avoidance of doubt, the intent of the Parties is that each Party shall [**] (or “[**]”) in any Other Collaboration Litigation matter that is [**] subject to the following:

(A) If the Active Party [**] the intent is that the Active Party shall be responsible for [**] percent ([**]%) of the first [**] Dollars (USD\$[**]) of Legal Expenses [**].

(B) If the Active Party [**] the intent is to ensure that all Legal Expenses are borne by the Parties [**].

5.6 Citizen’s Petitions and Citizen Petition Litigation. The JSC shall review and agree on the appropriate course of action with respect to citizen’s petition proceedings and litigation. The Parties agree that all Legal Expenses associated with citizen’s petition proceedings shall be allocated according to the Parties’ respective Allocable Legal Expense Shares.

5.7 Patent Term Extensions. The Parties shall cooperate, if necessary and appropriate, with each other in gaining patent term extensions wherever applicable to Patent Rights controlled by either Party that cover a Product. The Parties shall use reasonable efforts to agree upon a joint strategy relating to patent term extensions, but, in the absence of mutual agreement with respect to any extension issue, the Patent Rights or the claims of the Patent Rights shall be selected, by the Party owning or controlling the Patent Rights, on the basis of the scope, enforceability and remaining term of the Patent Right in the relevant jurisdiction. All filings for such extensions shall be made by the Party owning or controlling such Patent Rights.

5.8 Patent Marking. Baxter shall be responsible for complying with patent marking statutes in the applicable country in the Territory in which a Product is sold by Baxter, its Affiliates or its sublicensees.

5.9 Participation of Other Persons in the Collaboration. Except as the Parties may otherwise agree in writing, each of Baxter and Momenta shall be responsible for executing an appropriate agreement with each employee, individual contractor, consultant or agent (including, for purposes of clarity, individuals who regularly work for Affiliates of Baxter or Momenta), as well as Third Parties working on their respective behalves on the Collaboration, including a provision requiring such employee, individual contractor, consultant, agent, or Third Party to assign to Baxter or Momenta, respectively, all Know-How and Patent Rights which he or she develops or conceives and/or reduces to practice in the course of his or her work on the Collaboration so that such Know-How and Patent Rights are Controlled by Baxter or Momenta, respectively. Each Party shall use Commercially Reasonable and Diligent Efforts to enforce the terms of their respective agreements described in this Section 5.9. Upon written request, each Party shall make available to the other Party copies of any material agreements with contractors or other Third Parties with respect to Third Party Payments authorized by the JSC under Section 4.4.

5.10 Disclosure of Know-How.

(a) In connection with the activities contemplated by this Agreement, the Parties anticipate that certain Know-How will be disclosed between the Parties. In order to keep accurate records of what each Party considers to be its Know-How, and for the Parties to monitor their obligations with respect to such Know-How, the Parties shall establish an electronic registry (the “Know-How Database Registry”) accessible to both Parties.

(b) Each Party shall designate a Know-How Database Registry manager, whose responsibility it will be to [**]. Each entry shall [**]. Upon entry of a document into the Know-How Database Registry, the Know-How Database Registry manager for the entering Party shall [**]. Such notification shall be through an email sent either by the entering Party’s Know-How Database Registry manager or through an automated system wherein an email is sent by the Know-How Database Registry following entry of the document.

(c) The reviewing Party’s Know-How Database Registry manager shall have [**], and either [**]; however, in the case of Technology Transfer documentation, the reviewing Party’s Know-How Database Registry manager shall have [**], due to the large amount of documents in the Technology Transfer documentation. If the reviewing Party [**], such document shall be deemed Know-How of the entering Party. If the reviewing Party [**], the reviewing Party shall provide written notice to [**] shall be entered in the Know-How Database Registry referencing the [**].

(d) At such time as the Parties have [**], the original entering Party shall respond to the [**] provided in the Know-How Database Registry. The Parties shall discuss in a timely manner the [**] shall be entered into the Know-How Database Registry. If the Parties are not able to [**] of the entering party, the dispute shall be resolved by senior management of the Parties and if senior management is not able to come to a prompt resolution, the dispute shall be resolved pursuant to the terms set forth in Section 12.11.

**ARTICLE 6.
LICENSES; CHARACTERIZATION OPTION AND EXCLUSIVITY**

6.1 Licenses to Baxter.

(a) Development License. Subject to the terms and conditions of this Agreement, Momenta hereby grants to Baxter, a co-exclusive (co-exclusive with Momenta), right and license, in the Field, in the Territory under the Momenta Intellectual Property solely to perform its activities under the applicable Product Work Plan(s) and Commercialization Plan(s) to Develop and Commercialize the Products.

(b) Product License. Subject to the terms and conditions of this Agreement (to the extent this Section 6.1(b) conflicts with Section 6.1(a) above, this Section 6.1(b) shall control), Momenta hereby grants to Baxter, an exclusive, right and license, in the Field, in the Territory, with the right to grant sublicenses solely as agreed to by the Parties, under the Momenta Intellectual Property solely to (i) make (and have made), use,

and import the Products for commercial sale and (ii) sell, offer for sale and have sold the Products.

(c) Covenant . Baxter shall use such Momenta Intellectual Property solely for the purposes of exercising its rights and performing its obligations under this Agreement.

6.2 Licenses to Momenta .

(a) Commercialization License . Subject to the terms and conditions of this Agreement, Baxter hereby grants to Momenta, a co-exclusive (co-exclusive with Baxter), right and license, in the Field, in the Territory, under the Baxter Intellectual Property solely to (i) perform its activities under the applicable Product Work Plan(s) to Develop the Products and (ii) to the extent Momenta has rights to Commercialize the Products pursuant to Section 2.7(b) to perform its activities under the applicable Commercialization Plan.

(b) Development License . Subject to the terms and conditions of this Agreement (to the extent this Section 6.2(b) conflicts with Section 6.2(a) above, this Section 6.2(b) shall control), Baxter hereby grants to Momenta, an exclusive right and license, in the Field, in the Territory, with the right to grant sublicenses solely as agreed to by the Parties, under the Baxter Intellectual Property solely to make (and have made), use, and import the Products for Development.

(c) Covenant . Momenta shall use such Baxter Intellectual Property solely for the purposes of exercising its rights and performing its obligations under this Agreement.

6.3 Collaboration Intellectual Property Cross License . Each Party grants to the other Party a non-exclusive, royalty-free, worldwide right and license, with the right to grant sublicenses, to practice the Collaboration Intellectual Property outside the scope of the Collaboration.

6.4 In-Licensed Technology . After the Effective Date, if either Party, its Affiliates, or sublicensees identify the need for, or are otherwise offered, a license, covenant not to sue or similar rights to Third Party Patent Rights or Know-How that such Party or its Affiliates in good faith believes are (a) necessary to avoid infringement or misappropriation of such Third Party Patent Right or Know-How based on the Development or Commercialization of the applicable Product or (b) necessary or useful for the Development or Commercialization of the applicable Product, prior to commencing negotiations or entering into an agreement with respect to any such Third Party license or covenant, such Party shall promptly notify the other Party. The Parties shall thereafter conduct good faith discussions, by way of the JSC, regarding whether such Third Party Patent Rights or Know-How are necessary or useful for the Development and Commercialization of the Product. The Parties shall agree on which Party shall negotiate the license, including any associated Third Party Payments, provided, however, that no definitive license agreement shall be signed by either Party with regard to such rights without the other Party's written consent, which shall not be unreasonably withheld or delayed.

6.5 Retained Rights . Any rights of Momenta not expressly granted to Baxter under the provisions of this Agreement shall be retained by Momenta and any rights of Baxter not

expressly granted to Momenta under the provisions of this Agreement shall be retained by Baxter.

6.6 Exclusive Collaboration. During the Term of the Agreement, Momenta and Baxter each agree, respectively, that they shall, and shall ensure that their respective Affiliates and sublicensees shall, collaborate exclusively on the Development and Commercialization of the Products and shall not develop or sell a Competing Product to a Product on their own behalf or on behalf of a Third Party. Should a Party fail to comply with this Section 6.6, such failure shall be deemed a material breach of the Agreement, providing the non-breaching Party with the right to terminate the Agreement with respect to the Product for which the Competing Product was developed.

6.7 Protection of Baxter Proprietary Information. In connection with its Development Activities in the Collaboration, Momenta will have access to Baxter's proprietary technology relating to [**]. Such [**] is primarily related to the methods used to develop and commercialize [**]. In order to protect Baxter's proprietary information, during the Term of the Agreement and for a period of [**] thereafter, Momenta agrees [**].

6.8 Bankruptcy. All rights and licenses granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. Upon the bankruptcy of a Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

ARTICLE 7. CONFIDENTIAL INFORMATION

7.1 Confidentiality. Except as contemplated by this Agreement, each Party shall hold in confidence and shall not publish or otherwise disclose and shall not use for any purpose (a) any Confidential Information of the other Party disclosed to it pursuant to the terms of this Agreement, (b) the terms of this Agreement, and (c) the transactions contemplated hereby until ten (10) years after the expiration or termination of this Agreement. The members of the JSC and any Sub-Committees shall use pricing and other competitive commercial information provided by the other Party solely for purposes of the Collaboration and shall not share such information more broadly within their organizations.

7.2 Public Disclosure. The Parties have attached hereto as Exhibit 7.2, a mutually acceptable press release announcing the Collaboration (the "Initial Press Release"). The JSC shall review, from time to time, proposed disclosures of the Parties and consent for such disclosures shall not be unreasonably withheld. Except as otherwise required by Law (as reasonably determined by counsel) and with respect to JSC approved disclosures, as well as the Initial Press Release as agreed upon between the Parties, neither Party shall issue a press release or make any other public disclosure of the terms of this Agreement without the prior approval of

such press release or public disclosure by the other Party. Each Party shall submit any such press release or public disclosure to the other Party, and the receiving Party shall have five (5) business days from receipt to review and approve any such press release or public disclosure, which approval shall not be unreasonably withheld. If the receiving Party does not respond to the other Party within such five (5) business day period, the press release or public disclosure shall be deemed approved. In addition, if a public disclosure is required by Law, including without limitation in a filing with the Securities and Exchange Commission, the disclosing Party shall provide copies of the disclosure reasonably in advance of such filing or other disclosure for the non-disclosing Party's prior review and comment. The first approval of the contents of a press release or public disclosure shall constitute permission to use such contents subsequently without submission of the press release or public disclosure to the other Party for approval.

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

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

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

7.6 Prior Confidentiality Agreements. The Parties are parties to a Mutual Confidential Disclosure Agreement dated [**], as amended and a Community of Interest Letter dated [**], as amended on [**] (collectively, the "Prior Confidentiality Agreements"). The following shall be considered Confidential Information hereunder, subject to the exceptions in Section 1.26: (a) all

Confidential Information (as that term is defined in the Prior Confidentiality Agreements disclosed pursuant to the Prior Confidentiality Agreements, and (b) the Position Statements (as that term is defined in the Community of Interest Letter referenced above), which, notwithstanding anything in this Agreement to the contrary, shall also remain subject to the provisions of Section 3 of such Community of Interest Letter.

ARTICLE 8.
INDEMNIFICATION AND LIMITATION OF LIABILITY

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

8.2 Momenta Indemnification. Momenta agrees to defend Baxter and its Affiliates, and their respective agents, directors, officers and employees (the “Baxter Indemnitees”), at Momenta’s cost and expense, and will indemnify and hold harmless the Baxter Indemnites from and against any and all Third Party product liability related losses, costs, damages, fees or expenses (collectively, “Baxter Losses”) arising out of any act or omission of Momenta, its Affiliates, sublicensees, contractors or agents in connection with the development, use, manufacture, distribution or sale of a Product, including, but not limited to, any actual or alleged injury, damage, death or other consequence occurring to any person claimed to result, directly or indirectly, from the possession, use or consumption of, or treatment with, a Product, whether claimed by reason of breach of warranty, negligence, product defect or otherwise, and regardless of the form in which any such claim is made, provided that the foregoing indemnity shall not apply to the extent that any such Baxter Losses are attributable to (a) Baxter’s material breach of

this Agreement or an applicable Work Plan, or (b) the gross negligence or willful misconduct of the Baxter Indemnitees. In the event of any such claim against any Baxter Indemnitee, Baxter shall promptly notify Momenta in writing of the claim and Momenta shall manage and control, at its sole expense, the defense of the claim and its settlement. Notwithstanding the foregoing no settlements shall be finalized without obtaining Baxter's prior written consent, which shall not be unreasonably withheld, except that in the case of a settlement that does not require an admission or action on the part of Baxter, and does not harm Baxter or its ability to comply with its obligations hereunder, Baxter's consent shall not be required so long as Baxter is unconditionally released from all liability in such settlement. Baxter shall cooperate with Momenta and may, at its option and expense, be represented in any such action or proceeding. Momenta shall not be liable for any settlements, litigation costs or expenses incurred by Baxter Indemnitees without Momenta's written authorization.

8.3 Insurance. Each Party shall maintain insurance, including product liability insurance, with respect to its activities under this Agreement. Such insurance shall be in such amounts and subject to such deductibles as are prevailing in the industry from time to time, provided that, each Party shall maintain a minimum of an aggregate of [**] Dollars (USD\$[**]) in general comprehensive liability insurance and an aggregate of: (a) [**] Dollars (USD\$[**]) in product liability insurance [**] and (b) [**] Dollars (USD\$[**]) in product liability insurance no later than [**] days following [**].

8.4 No Consequential Damages. UNLESS RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR FROM A PARTY'S BREACH OF Article 6 OR Article 7, NO PARTY WILL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 8.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER THIS AGREEMENT.

ARTICLE 9. EXPORT

9.1 General. The Parties acknowledge that the exportation from the U.S. of materials, products and related technical data (and the re-export from elsewhere of U.S. origin items) may be subject to compliance with U.S. export laws, including without limitation the U.S. Bureau of Export Administration's Export Administration Regulations, the Federal Food, Drug and Cosmetic Act and regulations of the FDA issued thereunder, and the U.S. Department of State's International Traffic and Arms Regulations which restrict export, re-export, and release of materials, products and their related technical data, and the direct products of such technical data. The Parties agree to comply with all exports laws and to commit no act that, directly or indirectly, would violate any U.S. law, regulation, or treaty, or any other international treaty or

agreement, relating to the export, re-export, or release of any materials, products or their related technical data to which the U.S. adheres or with which the U.S. complies.

9.2 Delays. The Parties acknowledge that they cannot be responsible for any delays attributable to export controls that are beyond the reasonable control of either Party.

9.3 Assistance. The Parties agree to provide assistance to one another in connection with each Party's efforts to fulfill its obligations under this Article 9.

9.4 Other. The Parties agree not to export, re-export, or release any item that may be used in the design, development, production, stockpiling or use of chemical or biological weapons in or by a country listed in Country Group D: 3 of Part 370 to Title 15 of the U.S. Code of Federal Regulations as it may be updated from time to time.

ARTICLE 10. DEFAULT OR TERMINATION

10.1 Term. This Agreement shall be binding upon the Parties as of the Effective Date. The term of this Agreement (the "Term") shall commence on the Execution Date, unless earlier terminated as provided in this Article 10 (the date of any such termination, the "Termination Date"), shall continue in full force and effect, on a country-by-country and Product-by-Product basis until there is no remaining royalty, Profit Share or other payment obligation in such country with respect to such Product, at which time this Agreement shall expire in its entirety with respect to such Product in such country.

10.2 Termination by Baxter for Convenience. Baxter shall have the right to terminate the Agreement in whole or on a Product-by-Product basis at any time by providing written notice to Momenta.

(a) Termination following IND Acceptance. In the event Baxter elects to terminate the Agreement with respect to a Product within the sixty (60) day period following IND Acceptance of such Product, Baxter shall provide six (6) months prior written notice to Momenta.

(b) Termination prior to Phase II Clinical Trial or Phase III Clinical Trial. In the event Baxter elects to terminate the Agreement with respect to a Product more than sixty (60) days following IND Acceptance of such Product but before there is the first dosing in humans in a Phase II Clinical Trial or Phase III Clinical Trial for such Product, Baxter shall provide nine (9) months prior written notice to Momenta.

(c) Termination Prior to First Regulatory Approval. In the event Baxter elects to terminate the Agreement with respect to a Product following the first dosing in humans in a Phase II Clinical Trial or Phase III Clinical Trial for such Product, but prior to the first Regulatory Approval of the Product, Baxter shall provide twelve (12) months prior written notice to Momenta.

(d) Termination Following Regulatory Approval. In the event Baxter elects to terminate the Agreement with respect to a Product following the first Regulatory

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Approval of such Product, Baxter shall provide twelve (12) months prior written notice to Momenta.

(e) Partial Termination. In the event Baxter elects to terminate the Agreement with respect to one or more Products (but not the Agreement in whole) under this Section 10.2, Baxter's obligations will be as set forth in Section 10.6, and Momenta shall thereafter have the right, subject to the terms of this Agreement including, to the extent applicable, the limited licenses granted herein, to research, develop, manufacture, commercialize or license a Third Party to research, develop, manufacture, or commercialize such terminated Product(s).

10.3 Termination of Agreement by Momenta for Baxter's Termination of the Initial Products. Momenta shall have the right to terminate the Agreement in its entirety if Baxter elects to terminate both Initial Products prior to IND Acceptance by providing written notice to Baxter. Momenta shall thereafter have the right, subject to the terms of this Agreement including, to the extent applicable, the limited licenses granted herein, to research, develop, manufacture, or commercialize or license a Third Party to research, develop, manufacture or commercialize such former Initial Products.

10.4 Termination of Agreement for Breach of Material Obligation. Each Party shall have the right to terminate the Agreement in whole or on a Product-by-Product basis, as well on a country-by-country basis for breach of material obligations as follows:

(a) Except as provided for in Section 10.4(b) below, but subject to Section 2.7(b) and 2.7(c) above, in the event that a Party shall have breached or defaulted in the performance of any of its material obligations hereunder and such breach or default shall continue for a period of [**] days after written notice of such breach and the intent to terminate is provided to the breaching Party by the non-breaching Party, the non-breaching Party shall have the right, but not the obligation, to terminate this Agreement (or, as set forth in Section 6.6, the relevant Product) effective upon a second written notice to the breaching Party following the failure of the breaching Party to cure such breach or default during the [**] day period following the first written notice from the non-breaching Party.

For the avoidance of doubt, Baxter's failure to perform its obligations pursuant to Section 4.2(a) with respect to either GMP manufacturing or clinical (in human) studies shall constitute a material breach of the Agreement.

(b) Subject to Section 2.7(b) and (c), in the event that an alleged breach or default pertains to a failure to exercise Commercially Reasonable Efforts, the [**] day notice period in paragraph (a) above shall not commence until the following additional resolution process is not completed successfully:

(i) [**] days after a Party (the "Alleging Party") alleges a failure of the other Party to exercise Commercially Reasonable Efforts (the "Alleged Breaching Party"), the Alleged Breaching Party shall provide a written objective plan that documents how the Alleged Breaching Party either is performing its obligations

under the Agreement or will within the next [**] be performing its obligations in accordance with its duty to exercise Commercially Reasonable Efforts.

(ii) If the Alleging Party is not satisfied that the written plan objectively resolves the allegations, then the Alleging Party can elect to proceed under paragraph (a) without further resolution under this paragraph (b).

10.5 Termination for Bankruptcy. To the extent permitted under applicable Law, either Party may terminate this Agreement effective immediately with written notice if the other Party shall file for bankruptcy, shall be adjudicated bankrupt, shall file a petition under insolvency Laws, shall be dissolved or shall have a receiver appointed for substantially all of its property.

10.6 Consequences of Termination.

(a) Without limiting any other legal or equitable remedies that either Party may have, if this Agreement or a Product under the Agreement is terminated by Baxter pursuant to Section 10.2, by Momenta pursuant to Section 10.3, or is the result of a termination by Momenta for material breach by Baxter under Section 10.4, bankruptcy by Baxter under Section 10.5, or force majeure affecting Baxter under Section 12.6, the following provisions will take effect as of the effective date of such termination:

(i) Baxter will, using Commercially Reasonable Efforts, promptly [**](A) possession and ownership of all [**] reasonably necessary for and primarily related to the Development, manufacture or Commercialization of the terminated Product(s), (B) copies of all [**] reasonably necessary for and primarily related to the Development, manufacture or Commercialization of the terminated Product(s), including all [**] relating to the terminated Product(s), and (C) all [**] containing Confidential Information of Momenta; provided, however, that Baxter shall be entitled to retain one copy of all such Confidential Information for purposes of determining its obligations under this Agreement;

(ii) Baxter will either (A) appoint [**] as Baxter's and/or its Affiliates' agent for all terminated Product-related matters involving Regulatory Authorities; (B) serve as [**]; or (C) [**] for the period of time after termination necessary to allow for an orderly transition of the regulatory file or Regulatory Approval. Momenta agrees to use Commercially Reasonable Efforts to limit this obligation as is practicable under the circumstances;

(iii) If, at the time of termination, Baxter is then-currently performing process development or manufacturing activities for the terminated Products, Baxter shall upon Momenta's written request for a reasonable period of time [**] following receipt of written termination notice) and subject to Momenta's agreement to [**], as applicable) associated therewith: (A) continue to perform such process development activities and/or manufacturing activities for the terminated Product(s) and/or (B) use good faith reasonable efforts to effect a transfer of such activities to Momenta or a Third Party. If Momenta so requests,

Baxter will assign to Momenta any agreements with Third Parties reasonably necessary for and primarily relating to the Development, manufacture or Commercialization of the terminated Product(s) to which Baxter is a party to the extent permitted by the terms of such agreements; provided, however, that Baxter shall not be obligated to pay any amounts to the counterparty or to any Third Party in connection with such assignment;

(iv) Except as set forth below in Section 10.6(c), the licenses granted to Baxter and Momenta pursuant to Article 6 will terminate (except to the extent necessary to enable Baxter to perform its obligations under this Section 10.6); provided, however, that if the Agreement is terminated by Momenta pursuant to Section 10.4 due to Baxter's breach, (A) the licenses granted to Momenta under Sections 6.2 and 6.3 will survive for all Baxter Intellectual Property existing as of the date of termination and (B) Baxter shall grant Momenta (1) a [**] non-exclusive, sublicenseable [**] license under the Baxter Intellectual Property existing as of the date of termination and (2) an exclusive, sublicenseable license under the Collaboration Intellectual Property to make, have made, use, import, sell and have sold the terminated Products. Momenta shall have the right to prosecute and enforce any exclusively licensed Collaboration Patent Rights. [**] shall [**] of each Product which, but for the licenses granted hereunder, would infringe the [**] existing as of the Termination Date. The [**] shall be determined by the occurrence or non-occurrence of the events set forth in Section 10.6(c) but shall be [**] percent ([**]%) [**] set forth therein, and similarly shall [**] set forth in clauses (i), (ii) and (iii) of Section 10.6(c).

(v) Baxter will assign to Momenta all right, title and interest in the trademark(s) for the terminated Products and all goodwill associated therewith.

(vi) Baxter will, at Momenta's sole cost and expense, reasonably cooperate with Momenta, if requested, to transition all Clinical Development activities initiated by Baxter prior to the Termination Date;

(vii) Baxter shall submit payment to Momenta for any amounts paid by Momenta related to clinical (human) studies, GMP manufacturing activities, Development Expenses and Commercialization Costs incurred through the Termination Date for which Baxter is responsible for under the Agreement, and any milestones achieved as of the date of termination within sixty (60) days following receipt from Momenta of a detailed invoice therefore; and

(viii) Baxter will, at Momenta's sole cost and expense, return to Momenta all inventory of terminated Product in its possession as of the date of termination.

In addition, Momenta shall reimburse Baxter for [**] with the performance of the activities under subsections (i) and (ii), above.

(b) Without limiting any other legal or equitable remedies that either Party may have, if this Agreement or a Product under the Agreement is terminated by Baxter as

a result of a material breach by Momenta under Section 10.4, the following provisions will take effect as of the effective date of such termination:

(i) Momenta will, as soon as practicable, transfer to Baxter or its designee (A) copies of all data, reports, records and cell line materials in Momenta's possession or control relating to the Development, manufacture or Commercialization of the terminated Product(s), including all non-clinical and clinical data relating to the terminated Product(s), cell lines and (B) all records and materials in Momenta's possession or control containing Confidential Information of Baxter; and

(ii) The licenses granted to Momenta in Article 6 will terminate and the licenses and rights granted to Baxter under Article 6 will survive in accordance with their terms and subject to payment obligations set forth in Article 4.

(c) Termination Without Cause Reimbursement. If the Agreement or a Product was terminated by Baxter pursuant to Section 10.2, the licenses granted to Momenta under Sections 6.2 and 6.3 will survive for all Baxter Intellectual Property existing as of the date of termination and Baxter shall grant Momenta a [**], non-exclusive, sublicenseable (subject to the prior written consent of Baxter which consent shall not be unreasonably withheld, conditioned or delayed) license under the Baxter Intellectual Property existing as of the date of termination and an exclusive, sublicenseable license under the Collaboration Intellectual Property to make, have made, use, import, sell and have sold the terminated Products pursuant to the following terms:

(i) In the event Baxter terminates the Agreement with respect to a Product [**] of such Product as provided for at Section 10.2(b), Momenta shall [**] of such Product, [**] Baxter's Development Expenses with respect to the Development of such Product, [**].

(ii) In the event Baxter terminates the Agreement with respect to a Product [**] of such Product as provided for at Section 10.2(c) herein, Momenta shall [**] Baxter's Development Expenses and Commercialization Costs with respect to the Development and Commercialization of such Product, [**].

(iii) In the event Baxter terminates the Agreement with respect to a Product following [**] of such Product as provided for at Section 10.2(d) herein, Momenta shall [**] of such Product, [**] Baxter's Development Expenses and Commercialization Costs [**] with respect to the Development and Commercialization of such Product, [**].

10.7 Non-Exclusive Remedy. Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at Law or in equity, including, without limitation, the Parties' ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

10.8 Survival of Liability. Expiration or termination of this Agreement for any reason shall not release either Party from any liability that, at the time of such expiration or termination,

has already accrued or that is attributable to a period prior to such expiration or termination, nor preclude either Party from pursuing any right or remedy it may have hereunder or at Law or in equity with respect to any breach of this Agreement.

10.9 Survival. Upon termination of the Agreement as allowed for in this Article 10, the following sections of this Agreement shall survive: Article 1; Article 6 (to the extent provided for in Article 10); Article 7; Article 8; Article 9; Article 12; Section 4.2 (to the extent payments are earned but have not been paid prior to termination); Section 4.3 (to the extent following termination Sections 5.3, 5.4, 5.5 and 5.6 survive); Section 4.4 (to the extent Third Party Payments accrue prior to termination); Section 4.5 (to the extent a milestone is earned but has not been paid prior to termination); Section 4.6 (to the extent Royalties are earned but have not been paid prior to termination); Section 4.7 (to the extent accrued but not paid prior to termination); Section 4.9; Section 4.10 (with respect to actions and performance occurring prior to the Termination Date); Section 4.11, Section 4.12; Section 5.1, Section 5.2, Section 5.3; Section 5.4 (with respect to Enforcement Litigation initiated prior to termination); Section 5.5 (with respect to Other Collaboration Litigation initiated prior to termination); Section 5.6 (with respect to Citizen's Petitions proceedings initiated prior to termination); Section 5.7; Section 5.8; Section 6.5; Section 6.7; Section 6.8; Section 10.2 (e); Section 10.3, Section 10.4; Section 10.5; Section 10.6; Section 10.7; Section 10.8; Section 10.9; and Exhibit 12.11,

ARTICLE 11. REPRESENTATIONS, WARRANTIES AND COVENANTS

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

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

regulations and do not conflict with, or constitute a default under, any contractual obligation of it.

11.3 Compliance with Laws. Each Party shall carry out all work assigned to such Party in the applicable Product Work Plan (s) and its other obligations under this Agreement in material compliance with all applicable Laws, including (a) the Food, Drug, and Cosmetic Act and any applicable implementing regulations, and relevant foreign equivalents thereof; (b) GMPs; (c) all other applicable FDA guidelines and relevant guidelines of applicable regulatory authorities; (d) all other applicable laws and regulations, including all applicable federal, national, multinational, state, provincial and local environmental, health and safety laws and regulations in effect at the time and place of manufacture of a Product; and (e) all applicable export and import control laws and regulations.

11.4 Commercialization of Products. Baxter agrees, on behalf of itself and its Affiliates and sublicensees, not to materially and artificially discount the price of a Product solely to generate sales of other Baxter products.

11.5 Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF TECHNOLOGY OR PATENT CLAIMS, WHETHER ISSUED OR PENDING.

ARTICLE 12. MISCELLANEOUS

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

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

12.3 Assignments. Neither this Agreement nor any right or obligation hereunder may be assigned or delegated, in whole or part, by either Party without the prior written consent of the other or pursuant to subcontracting or sublicensing arrangements expressly contemplated herein; provided, however, that either Party may, without the written consent of the other, assign this Agreement and its rights and delegate its obligations hereunder in connection with the transfer or sale of all or substantially all of its business or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. Any purported assignment in violation of this Section 12.3 shall be void.

12.4 Independent Contractors. The relationship of the Parties hereto is that of independent contractors. The Parties hereto are not deemed to be agents, partners or joint

ventures of the others for any purpose as a result of this Agreement or the transactions contemplated thereby.

12.5 Notices. Any notice required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and sent by certified or registered mail, return receipt requested, postage prepaid, or sent by a nationally recognized overnight courier service, or sent by hand delivery, to the representative for such Party at the address set forth below for such Party. If a Party changes its representative or address, written notice shall be given promptly to the other Party of the new representative or address. Notice shall be deemed given on the third (3rd) business day after being sent in the case of delivery by mail, on the first (1st) business day after being sent in the case of delivery by overnight courier, and on the date of delivery in the case of delivery by hand. The addresses of the Parties and representatives are as follows:

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

With a copy to: Momenta Pharmaceuticals, Inc.
675 West Kendall Street
Cambridge, MA 02142
USA
Attn: General Counsel

If to Baxter, Inc.: Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015
USA
Attention: President BioScience

With a copy to: Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015
USA
Attention: General Counsel

12.6 Force Majeure. Neither Party shall be held liable or responsible to the other nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement (excluding payment obligations) to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control

of such Party including but not limited to fires, earthquakes, floods, embargoes, wars, acts of war (whether war is declared or not), terrorist acts, insurrections, riots, civil commotion, and other similar causes. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in a Work Plan that falls due during or subsequent to the occurrence of any of the disabilities referred to herein shall be automatically extended for a period of time equal to the period of such disability. Each Party shall immediately notify the other if, by reason of any of the disabilities referred to herein, it is unable to meet any deadline or time for performance specified in any Exhibit to this Agreement. The Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from this force majeure. If a condition constituting force majeure, as defined herein, exists for more than [**], either Party may terminate this Agreement.

12.7 Complete Agreement. Except with regards to the Community of Interest Letter Agreement between the Parties dated [**], as amended on [**] with respect to patent due diligence conduct by Baxter, it is understood and agreed between Momenta and Baxter that this Agreement constitutes the entire agreement, both written and oral, between the parties with respect to the subject matter hereof, and that all prior agreements respecting the subject matter hereof, whether written or oral, expressed or implied, shall be of no force or effect. No amendment or change hereof or addition hereto shall be effective or binding on either of the parties hereto unless reduced to writing and executed by the respective duly authorized representatives of Momenta and Baxter.

12.8 Quality Agreement. No later than [**] prior to Momenta or a Third Party engaged by Momenta engaging in cGMP activities, the Parties shall enter into a quality agreement relating to any cGMP Product to be supplied by Momenta.

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

12.10 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed to be an original and both together shall be deemed to be one and the same agreement.

12.11 Alternative Dispute Resolution. The Parties recognize that bona fide disputes may arise which relate to the Parties' rights and obligations under this Agreement. In attempting to resolve any such disputes, the matter shall first be elevated through each Party's respective senior management representatives (in the case of Baxter, to the President of Bioscience, in the case of Momenta to its President) for resolution. If the matter remains unresolved [**] after referral to such senior management representatives the matter shall be resolved by binding dispute resolution proceedings in accordance with the procedure set forth in Exhibit 12.11. Notwithstanding the foregoing, if the Parties are attempting to resolve a dispute that arises under Section 2.4(d), and the matter remains unresolved [**] after referral to such senior management representatives the third sentence of this Section 12.11 shall not apply but rather, Baxter shall be permitted to make the final decision with respect to the Clinical Development strategy.

12.12 HSR Act. The Parties shall use commercially reasonable efforts to promptly obtain any clearance required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (15 U.S.C. § 18a) (the “HSR Act”) for the consummation of this Agreement and the transactions contemplated hereby. Each Party shall furnish to the other Party reasonably necessary information and reasonable assistance as the other Party may request in connection with its compliance with the HSR Act, and any inquiries or requests for additional information in connection therewith. Baxter shall pay all costs and expenses related to any filing pursuant to the HSR Act. Baxter shall provide Momenta notice of achievement of the HSR clearance at such time (such date, the “HSR Clearance Date”) or promptly thereafter as practical. Other than the provisions of Article 11 and this Section 12.12, the rights and obligations of the Parties under this Agreement shall not become effective until the HSR Clearance Date, at which time it shall be immediately effective. In the event that the HSR Clearance Date has not been granted within one hundred twenty (120) days after the Execution Date, either Party may terminate this Agreement by written notice to the other Party. For the sake of clarity, none of the provisions of this Agreement, including without limitation Section 10.6, shall remain in effect after such termination.

[Signature Page Follows]

[Signature Page to Development, License and Option Agreement]

IN WITNESS WHEREOF, the Parties hereto have set their hand as of the date first above written.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ Craig Wheeler

Name: Craig Wheeler

Title: President and CEO

BAXTER INTERNATIONAL INC.

By: /s/ Ludwig N. Hantson

Name: Ludwig N. Hantson

Title: CVP/President BioScience

BAXTER HEALTHCARE CORPORATION

By: /s/ Ludwig N. Hantson

Name: Ludwig N. Hantson

Title: CVP/President BioScience

BAXTER HEALTHCARE SA

By: /s/ Kevin Holland

Name: Kevin Holland

Title: GM Emerging Markets

By: /s Sarah Byrne-Quinn

Name: Sarah Byrne-Quinn

Title: VP Business Development & Strategy

**Exhibit 1.89
Technical De-Risking Criteria**

1. Developed, scalable and transferrable upstream process including:
 - a. Achievement of sufficient, and mutually agreed to by the JSC, [**];
 - b. Demonstrated scalability from Benchtop ([**]) to Pilot Scale ([**]) and from Pilot Scale to Clinical Scale ([**]) with product specifications kept within the [**] process);
 - c. Confirmation of post-production cell line stability (cell culture productivity and genetic stability); and
 - d. [**] or [**] production medium.

Note: If the process utilizes a complex media (*i.e.* inclusion of cell culture media components like [**] (the “ additive ”)), reproducibility of the upstream process needs to be shown for [**] lots of any “additive” used

2. Developed, scalable and transferrable downstream process including:
 - a. Defined product specifications [**]
 - b. Defined impurity profile [**]
3. Acceptable protein purification [**] yield as determined by the JSC.
4. [**] plan for the Product, consistent with a biosimilar or interchangeable biologic development program, including, but not limited to, its development, manufacture, administration and use.

The [**] will have been determined to have been achieved upon the earlier of: (A) objective achievement the [**]; (B) JSC determination that the [**] for a Product has been achieved [**]; or (C) if [**] elects, [**], that it will proceed with the next stage [**] of Development of the Product.

For purposes of this Exhibit 1.89, the term “[**]” shall mean the sum of [**].

Exhibit 4.7
Examples of the Operation of the Royalty, Milestone and Profit Share Provisions

Key Assumptions

- 1) For illustration purposes the following scenarios of Launch, competition and sales are assumed per quarter, after Launch for one product:
 - a. Regulatory Approval Status: [**]
 - b. Net quarterly sales: [**]
 - c. Number of Competitors [**]

Momenta Royalty Calculation

- 2) Royalty payment calculation [**]:
 - a. Payments are calculated at the end of each quarter, beginning with the quarter in which Product is Launched
 - b. The table below summarizes the royalties under various conditions to be used in calculations:

Condition	[**] Competitors	[**] Competitors	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]

- c. In this example, in the quarter when \$[**] threshold is reached the following:



	Territory	Net Quarter Sales (\$M)	Cum. Sales (\$M)	Royalty Rate (Start of Quarter)	Royalty Rate (End of Quarter)	Calculation	Royalty Payment to Momenta (\$M)			
								Profit Share Scenario		
								Election	Election	Election
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]				[**]	\$ [**]	\$ [**]	\$ [**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]				[**]	\$ [**]	\$ [**]	\$ [**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]				[**]	[**]	[**]	[**]
Total		[**]	[**]				[**]	[**]	[**]	[**]

* Note: In this example, in the quarter when \$[**] threshold is reached the following calculation is used in order to determine the sales levels and their respective royalties:

[**]



**Exhibit 7.2
Initial Press Release**

FOR IMMEDIATE RELEASE

Media Contacts

Baxter
 Brian Kyhos, (847) 948-4210
 Deborah Spak, (847) 948-2349

Momenta
 Kari Watson,
 MacDougall Biomedical Communications, (781) 235-3068

Investor Contacts

Baxter
 Mary Kay Ladone, (847) 948-3371
 Clare Trachtman, (847) 948-3085

Momenta
 Beverly Holley, (617) 395-5189

TO DEVELOP AND COMMERCIALIZE FOLLOW-ON BIOLOGICS

DEERFIELD, ILL., and CAMBRIDGE, Mass., December 22, 2011 - Baxter International Inc. (NYSE:BAX) and Momenta Pharmaceuticals, Inc. (NASDAQ:MNTA) today announced that they have entered into a global collaboration to develop and commercialize follow-on biologic products, also known as biosimilars. Biosimilars replicate existing, branded biologics used in the treatment of a variety of diseases including cancer, autoimmune disorders and other chronic conditions. With this collaboration, Baxter will leverage its leading clinical development and biologic manufacturing expertise, global leadership in sterile injectables and global commercial capabilities, while Momenta will provide its expertise in high-resolution analytics, characterization, and product and process development.

Under the terms of the agreement, Baxter will make an upfront cash payment of \$33 million to Momenta related to the collaboration for up to six follow-on biologic compounds. Baxter may make additional payments over the next several years for the development of the compounds, contingent upon the achievement of technical, development and regulatory milestones with respect to all six products.

“Baxter is an established leader in biologic treatments for a variety of diseases. As biologics have become an increasingly important part of patient care, the collaboration with Momenta allows us to tap both companies’ expertise to expand access to these important therapies,” said Ludwig Hantson, President of Baxter’s BioScience business. “The collaboration complements Baxter’s early-stage pipeline and allows the company to expand its leadership in biologics at a time when the global regulatory pathway for approval is becoming more clear.”

“Momenta and Baxter share a common goal in this collaboration -to create interchangeable biologic products by taking advantage of Momenta’s innovative physicochemical and biologic characterization capabilities, coupled with a quality-by-design approach to process development,” commented Craig Wheeler, President and CEO of Momenta. “We are thrilled to have Baxter as a partner. Baxter’s global footprint and extensive development, manufacturing and commercial expertise are exactly what we need to succeed in building a leading follow-on biologics business.”

Baxter and Momenta expect to close the transaction in the first quarter of 2012, subject to customary closing conditions including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

About Baxter International Inc.

Baxter International Inc., through its subsidiaries, develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex drugs. Momenta is applying its technology to the development of generic versions of complex drug products, as well as to the discovery and development of novel drugs. Momenta was founded in 2001 and is headquartered in Cambridge, Mass. This release includes forward-looking statements concerning a collaboration agreement between Baxter International Inc. and Momenta Pharmaceuticals, Inc., including expectations with respect to the closing of the transaction and milestone payments. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: satisfaction of closing conditions, including expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act; satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; product quality or patient safety issues; and other risks identified in each of the company's most recent filings on Form 10-K and

other SEC filings. Neither Baxter nor Momenta undertakes to update its forward-looking statements.

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Exhibit 12.11
Alternative Dispute Resolution

- (a) The Parties shall attempt to resolve any and all disputes, claims or controversies arising out of or relating to this Agreement promptly by negotiation between executives pursuant to Section 12.11 of the Agreement who have authority to settle the controversy. If such disputes, claims or controversies are not resolved through such negotiation, then they shall be submitted for final and binding arbitration pursuant to the arbitration clause set forth below. Either Party may initiate arbitration with respect to the matters submitted to negotiation by filing a written demand for arbitration at any time following the initial negotiation session.
- (b) To the extent not resolved by the above noted negotiation process between the executives of the Parties, any dispute, claim or controversy arising out of or relating to this Agreement or the breach, termination, enforcement, interpretation or validity thereof, including the determination of the scope or applicability of this Agreement to arbitrate, shall be determined by arbitration in the city of the defendant, in the language in which the contract was written. The arbitration shall be administered by the International Institute for Conflict Prevention & Resolution (CPR) pursuant to its Arbitration Rules and Procedures. References herein to any arbitration rules or procedures mean such rules or procedures as amended from time to time, including any successor rules or procedures, and references herein to the CPR include any successor thereto. The arbitration shall be before [**] arbitrators. Each Party shall designate one arbitrator in accordance with the “screened” appointment procedure provided in Rule 5.4 of the CPR Rules. The [**] Party-appointed arbitrators will select the [**], who will serve as the panel’s chair or president. All [**] arbitrators shall have experience in licensing and development of biologic products. This arbitration provision, and the arbitration itself, shall be governed by the laws of the state of Delaware and the Federal Arbitration Act, 9 U.S.C. §§ 1-16.
- (c) Consistent with the expedited nature of arbitration, each Party will, upon the written request of the other Party, promptly provide the other with copies of documents on which the producing Party may rely in support of or in opposition to any claim or defense or in support of its position. At the request of a Party, the arbitrators shall have the discretion to order examination by deposition of witnesses to the extent the arbitrator deems such additional discovery relevant and appropriate. It is contemplated that depositions will be appropriate in disputes involving an allegation of breach of contract, termination rights, or a claim for damages. Depositions shall be limited to a maximum of [**] per Party and shall be held within [**] of the grant of a request. Additional depositions may be scheduled only with the permission of the arbitrators, and for good cause shown. Absent a showing of good cause, each deposition shall be limited to a maximum of [**] duration. All objections are reserved for the arbitration hearing except for objections based on privilege and proprietary or confidential information. The Parties shall not utilize any other discovery mechanisms, including international processes and U.S. federal statutes, to obtain additional evidence for use in the arbitration. Any dispute regarding discovery, or the relevance or scope thereof, shall be determined by the arbitrators, which
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determination shall be conclusive. Absent a showing of good cause, all discovery shall be completed within [**] following the appointment of the arbitrators. The Arbitrators shall exercise judgment to assure that the scope of discovery is appropriately proportionate to the magnitude of the dispute and its relevance to resolution of the dispute. For example, in resolving a JSC deadlock that does not involve a claim for damages or breach of contract, discovery may not require five (5) depositions or significant document disclosure and the briefing of the proposed Positions (as defined below in paragraph (d)) along with factual and expert support may be sufficient.

- (d) Within [**] days of the later of (i) [**] or (ii) [**], the Parties shall exchange their final arguments as to the matter(s) under dispute (“Position”) together with a brief or other written memorandum supporting the merits of their Position. With respect to disputes involving a failure of the JSC to reach consensus under Section 2.4(e) that are not expressly assigned to a Party under the Agreement and have not been resolved under Section 2.11, the arbitration panel shall select the Position which most closely reflects a commercially reasonable interpretation of the terms of the Agreement as the binding Position to be executed by the Parties. In making their selection the arbitrators shall not modify the terms or conditions of either Party’s final Position nor shall the arbitrators combine provisions from both final Positions. With respect to all other disputes, the arbitrators shall have the authority to award damages or issue a determination resolving the dispute not limited to the specific positions requested by each Party. In making their decision, the arbitrators shall consider the terms and conditions of the Agreement, the relative merits of the final Proposals, and the written and oral arguments of the Parties. In the event the arbitrators seek the guidance of the law of any jurisdiction; the law of the State of Delaware, with the exception of its choice of law provisions, shall govern.
- (e) The panel of arbitrators shall have no power to award non-monetary or equitable relief of any sort. The arbitrators will have no authority to award punitive or other damages not measured by the prevailing Party’s actual damages, except as may be required by statute. Each Party expressly waives and foregoes any right to consequential, punitive, special, exemplary or similar damages or lost profits. The arbitrators shall have no power or authority, under the CPR Rules for Non-Administered Arbitration or otherwise, to relieve the Parties from their agreement hereunder to arbitrate or otherwise to amend or disregard any provision of this Agreement. The award of the arbitrators shall be final, binding and the sole and exclusive remedy to the Parties. Either Party may seek to confirm and enforce any final award entered in arbitration, in any court of competent jurisdiction. The cost of the arbitration, including the fees of the arbitrators, shall be borne [**].
- (f) If an arbitral award does not impose an injunction on the losing Party or contain a money damages award in excess of [**] Dollars (USD\$[**]), then the arbitral award shall not be appealable and shall only be subject to such challenges as would otherwise be permissible under the Federal Arbitration Act, 9 U.S.C. §§ 1-16. In the event that the arbitration does result in an arbitral award, which imposes an injunction or a monetary award in excess of [**] Dollars (USD\$[**]), such award may be appealed to a tribunal of appellate arbitrators via the CPR Arbitration Appeal Procedure.
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- (g) Except as may be required by law, neither a Party nor an arbitrator may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of both Parties.
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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

ASSET PURCHASE AGREEMENT

by and between:

MOMENTA PHARMACEUTICALS, INC. ,
a Delaware corporation; and

VIRDANTE PHARMACEUTICALS, INC.,
a Delaware corporation.

Dated as of December 2, 2011

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT is entered into as of December 2, 2011, by and between: **MOMENTA PHARMACEUTICALS, INC.**, a Delaware corporation (the “**Purchaser**”) and **VIRDANTE PHARMACEUTICALS, INC.**, a Delaware corporation (the “**Seller**”). Certain capitalized terms used in this Agreement are defined in Exhibit A.

RECITALS

A. The Seller wishes to sell to the Purchaser and the Purchaser wishes to purchase from the Seller the Transferred Assets (as defined in Section 1.1), representing substantially all of the assets of the Seller, for the consideration, on the terms, and subject to the conditions, set forth in this Agreement.

AGREEMENT

The parties to this Agreement, intending to be legally bound, agree as follows:

1. SALE OF TRANSFERRED ASSETS; RELATED TRANSACTIONS.

1.1 Sale of Transferred Assets. At the Closing (as defined in Section 1.7), the Seller shall sell, assign, transfer, convey and deliver to the Purchaser, and the Purchaser shall purchase and acquire from the Seller, all of the Transferred Assets, free of any Encumbrances, on the terms and subject to the conditions set forth in this Agreement. For purposes of this Agreement, “**Transferred Assets**” shall mean the following assets and properties of the Seller existing as of the Closing (but excluding the Excluded Assets (as defined below)):

(a) Intellectual Property and Intellectual Property Rights : All of the Intellectual Property and Intellectual Property Rights that are owned or controlled by the Seller and that are or were used in, necessary for the conduct of, or related to, the Business, including the Intellectual Property and Intellectual Property Rights identified on Schedule 1.1(a), together with the goodwill associated with the Transferred Assets (the Intellectual Property, Intellectual Property Rights and goodwill referred to in this Section 1.1(a) collectively being referred to in this Agreement as the “**Transferred IP**”);

(b) Tangible Assets : All tangible assets set forth on Schedule 1.1(b);

(c) Contracts : All rights of the Seller under the Seller Contracts set forth on Schedule 1.1(c) (the Seller Contracts referred to in this Section 1.1(c) being referred to as the “**Transferred Contracts**”);

(d) Claims : All Claims (including Claims for past infringement of Transferred Assets and Claims for insurance benefits, rights and proceeds) of the Seller against other Persons relating to the Transferred Assets (regardless of whether or not such Claims have been asserted by the Seller), and all rights of indemnity, warranty rights, rights of contribution, rights to refunds, rights of reimbursement and other rights of recovery possessed by the Seller (regardless of whether such rights are currently exercisable) relating to the Transferred Assets; and

(e) Records, Etc. : All of Seller’s records set forth on Schedule 1.1(e) (such documents referred to in this Section 1.1 (e) being referred to as the “**Transferred Records**”).

1.2 Excluded Assets. Notwithstanding anything to the contrary contained in this Agreement, the parties agree that the Seller is not selling, assigning, transferring, conveying or delivering to the

Purchaser, and the Transferred Assets shall not include, any of the Excluded Assets, and such Excluded Assets shall remain the property of the Seller after the Closing.

1.3 Purchase Price. As consideration for the sale, assignment, transfer, conveyance and delivery of the Transferred Assets to the Purchaser:

(a) on the date hereof (the “ **Closing Date** ”), the Purchaser shall pay, or cause to be paid, to the Seller, in cash, a total of \$4,500,000, by wire transfer of immediately available funds to an account number provided to the Purchaser by the Seller; and

(b) subject to any right of setoff that any Purchaser Indemnitee may be entitled to exercise (pursuant to Section 4.2(d) or otherwise), the Purchaser shall pay, or cause to be paid, to the Seller the amounts on the dates set forth below (collectively, the “ **Milestone Payments** ”) if and solely to the extent the Milestones are achieved in accordance with the terms and conditions of Exhibit F hereto:

(i) on the Milestone Payment Date (as defined on Exhibit F hereto) for Milestone #1A as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**];

(ii) on the Milestone Payment Date for Milestone #1B as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**];

(iii) on the Milestone Payment Date for Milestone #1C as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**];

(iv) on the Milestone Payment Date for Milestone #2A as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**];

(v) on the Milestone Payment Date for Milestone #2B as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**];

(vi) on the Milestone Payment Date for Milestone #2C as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**];

(vii) on the Milestone Payment Date for Milestone #3A as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**];

(viii) on the Milestone Payment Date for Milestone #3B as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**]; and

(ix) on the Milestone Payment Date for Milestone #3C as set forth on Exhibit F hereto, the Purchaser will pay to the Seller an amount equal to \$[**].

1.4 Assumption of Certain Liabilities.

(a) Subject to Section 1.4(b), the Purchaser shall not assume any Liabilities of the Seller (whether or not related to the Transferred Assets or the Business), including without limitation: (i) any Liabilities of the Seller relating to the Excluded Assets; (ii) any Tax Liabilities of the Seller, except to the extent allocated to the Purchaser under Sections 1.5 and 5.4(b); (iii) any Liabilities of the Seller relating to accounts payable or other indebtedness; (iv) any wages or salaries or other Liabilities relating to employment (or termination of employment) of any employees of the Seller (including accrued

vacation); (v) any Liabilities under any Seller Contracts (other than Liabilities relating to Transferred Contracts that arise after the Closing Date); or (vi) any other Liabilities of the Seller.

(b) Notwithstanding Section 1.4(a) or any other provision of this Agreement to the contrary, from and after the Closing, the Purchaser shall assume, discharge and perform as and when due all of the obligations of the Seller under the Transferred Contracts, including assuming liability for any claims based on or relating to the transfer of the Product Materials acquired from [**] by the Seller to the Purchaser pursuant to this Agreement, but in any case only to the extent that such obligations: (i) arise after the Closing Date and (ii) do not arise from or relate to any breach by the Seller of any provision of any of such Transferred Contracts; and (iii) do not arise from or relate to any event, circumstance or condition occurring or existing on or prior to the Closing Date that, with notice or lapse of time, would constitute or result in a breach of any of such Transferred Contracts (the “**Assumed Liabilities**”). Notwithstanding the terms of that certain Consent Letter by and among the Purchaser, the Seller and The Rockefeller University, dated November 30, 2011 (the “**Consent Letter**”), for purposes of clarity, the Seller acknowledges and agrees that the Purchaser is only assuming the obligations of the Seller under the Rockefeller License Agreement and the Ancillary Agreements (as defined in the Consent Letter) subject to the limitations set forth in the prior sentence and, if any conflict exists between the Consent Letter and this Agreement, this Agreement shall control as between Seller and Purchaser.

1.5 Transaction Taxes. The Purchaser and the Seller shall each be liable for one-half (1/2) of any sales Taxes, use Taxes, transfer Taxes or similar Taxes, charges or fees (“**Transaction Taxes**”) that may become payable by the party under applicable Law in connection with the conveyance and transfer of the Transferred Assets to the Purchaser or in connection with any of the other Transactions. The Purchaser and the Seller shall each use reasonable efforts to avail themselves of any available exemptions from any such Transaction Taxes and to cooperate with each other in providing any information and documentation that may be reasonably necessary to obtain such exemptions.

1.6 Allocation. The Purchase Price Allocation set forth on Schedule 1.6 (the “**Allocation Schedule**”) shall be used by the Seller and the Purchaser for all purposes, including preparation and filing of Internal Revenue Service Form 8594, and no party hereto shall take or assert any position inconsistent therewith.

1.7 Closing .

(a) The closing of the sale of the Transferred Assets to the Purchaser and the other Transactions contemplated by this Agreement (the “**Closing**”) shall take place immediately following the execution and delivery of this Agreement.

(b) At the Closing, the Seller shall cause to be delivered to the Purchaser:

(i) a Bill of Sale and Assignment Agreement, in substantially the form of Exhibit B, duly executed by the Seller;

(ii) evidence satisfactory to the Purchaser of the requisite approval by the Seller, the board of directors and stockholders of the Seller of the sale of the Transferred Assets to the Purchaser and the other Transactions;

(iii) such bills of sale, endorsements, assignments and other documents as may (in the reasonable judgment of the Purchaser or its counsel) be necessary to assign, convey, transfer and deliver to the Purchaser good and valid title to the Transferred Assets free and clear of any Encumbrances;

applicable; (iv) evidence satisfactory to the Purchaser of the receipts for all Consents for the Transferred Contracts, if

Purchaser, in substantially the form of Exhibit C hereto;

(vi) a letter agreement from The Rockefeller University, in substantially the form of Exhibit D hereto; and

(vii) a consent from [**], in substantially the form of Exhibit H hereto; and

(viii) a waiver and release from each of John W. Ripple, External GC Law Group and Wilmer Cutler Pickering Hale and Dorr LLP, in substantially the form of Exhibit I hereto.

(c) At the Closing, the Purchaser shall cause to be delivered to the Seller an Assignment and Assumption Agreement, in substantially the form of Exhibit E, duly executed by the Purchaser.

1.8 Discharge of Liabilities. On the Closing Date, the Seller shall have repaid and discharged all indebtedness for borrowed money owed by the Seller and all ancillary obligations thereto (including all interest accrued thereon and all fees, charges or premiums associated therewith). The Seller shall not make any final distribution of the proceeds received pursuant to this Agreement until the Seller has discharged (or reserved reasonably adequate funds to satisfy) all Liabilities of the Seller.

2. REPRESENTATIONS AND WARRANTIES OF THE SELLER .

The Seller represents and warrants, to and for the benefit of the Purchaser Indemnitees, as follows:

2.1 Due Organization; No Subsidiaries; Capitalization .

(a) The Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Seller is not required to be qualified, authorized, registered or licensed to do business as a foreign corporation in any jurisdiction other than the jurisdictions listed in Part 2.1 of the Disclosure Schedule, except where failure to be qualified would not reasonably be expected to have a Material Adverse Effect. The Seller is in good standing as a foreign corporation in each of the jurisdictions listed in Part 2.1 of the Disclosure Schedule, except where failure to be qualified would not reasonably be expected to result in a Material Adverse Effect. The Seller does not have any subsidiaries and does not own, beneficially or otherwise, any shares or other securities of, or any direct or indirect interest of any nature in, any other Entity. The Seller has the power and authority to own, lease and operate the Transferred Assets and to carry on the Business as previously conducted and as now being conducted. The Seller has not conducted any business under or otherwise used, for any purpose or in any jurisdiction, any fictitious name, assumed name, trade name or other names, other than "Centaurus Pharmaceuticals, Inc."

(b) The authorized capital stock of Seller consists of 60,750,000 shares of Common Stock, of which 1,775,750 shares are issued and outstanding and 47,750,000 shares of Preferred Stock, all of which are designated as Series A Preferred Stock and 30,075,000 shares of which are issued and outstanding.

2.2 Financial Statements . The Seller has provided to the Purchaser the Financial Statements. The Financial Statements fairly present the financial position of the Seller as of the dates thereof, consistent with the books and records of the Seller. Since the Balance Sheet Date, there has occurred no event or development which, individually or in the aggregate, has had, or could reasonably be expected to have in the future, a Material Adverse Effect.

2.3 Undisclosed Liabilities .

(a) The Seller has no Liability (whether known or unknown, whether absolute or contingent, whether liquidated or unliquidated and whether due or to become due), except for (i) liabilities reflected or reserved against on the Balance Sheet, (ii) Liabilities which have arisen since the Balance Sheet Date in the ordinary course of business and (iii) contractual and other liabilities incurred in the ordinary course of business which are not required by generally accepted accounting principles in the United States to be reflected on a balance sheet, (iv) liabilities which have been incurred in connection with the transactions contemplated by this Agreement and (v) liabilities disclosed in Section 2.3 of the Disclosure Schedule.

(b) The Seller is not now insolvent, nor will it be rendered insolvent by any of the Transactions. As used in this section, “**insolvent**” means the debts and other probable Liabilities of an Entity exceed the sum of the present fair saleable value of the assets of such Entity. Immediately after giving effect to the consummation of the Transactions: (i) the Seller will be able to pay its Liabilities as they become due in the usual course of its business; and (ii) the Seller will have assets (calculated at fair market value) that exceed its Liabilities.

2.4 Intellectual Property.

(a) Part 2.4(a) of the Disclosure Schedule accurately identifies: (i) each item of Registered IP in which the Seller has or purports to have an ownership interest of any nature (whether exclusively, jointly with another Person, or otherwise); (ii) the jurisdiction in which such item of Registered IP has been registered or filed and the applicable registration or serial number; and (iii) any other Person that has an ownership interest in such item of Registered IP and the nature of such ownership interest.

(b) Part 2.4(b) of the Disclosure Schedule accurately identifies: (i) each Contract pursuant to which any Intellectual Property Right or Intellectual Property that was previously used in or is currently used in the Business is or has been licensed, sold, assigned, or otherwise conveyed or provided to the Seller (other than: (A) agreements between the Seller and its employees in the Seller’s standard form thereof and (B) non-exclusive licenses to third-party software that (1) are not incorporated into, or used in the development, manufacturing, testing, distribution or support of, any Transferred Asset and that are not otherwise material to the Business; and (2) that are generally available to the public and impose no future monetary obligation on the Seller); and (ii) whether the licenses or rights granted to Seller in each such Contract are exclusive or non-exclusive (the “**Third-Party IP**”). The Seller has made available to the Purchaser accurate and complete copies of each Contract identified or required to be identified in Part 2.4(b) of the Disclosure Schedule.

(c) Part 2.4(c) of the Disclosure Schedule accurately identifies each Contract pursuant to which any Person has been granted any license under, or otherwise has received or acquired any right (whether or not currently exercisable) or interest in, any Transferred Product or Transferred IP.

(d) Part 2.4(d) of the Disclosure Schedule contains a complete and accurate list and summary of all royalties, fees, commissions, and other amounts payable by the Seller to any other Person

(other than sales commissions paid to employees according to the Seller's standard commissions plan) upon or for the manufacture, sale, or distribution of any Transferred Product or the use of any Transferred IP.

(e) The Seller has made available to the Purchaser a complete and accurate copy of each standard form of Contract related to Intellectual Property or Intellectual Property Rights used by the Seller at any time in connection with the Business, including each standard form of: (i) employee agreement containing any assignment or license of Intellectual Property Rights; (ii) consulting or independent contractor agreement containing any intellectual property assignment or license of Intellectual Property Rights; and (iii) confidentiality or nondisclosure agreement.

(f) The Seller exclusively owns all right, title, and interest to and in the Transferred IP free and clear of any Encumbrances (other than licenses and rights granted pursuant to the Contracts identified in Part 2.4(b) of the Disclosure Schedule). The Seller has a valid right to use and otherwise exploit, and to license others to use and otherwise exploit, all Third-Party IP identified or required to be identified in Part 2.4(b) of the Disclosure Schedule. Without limiting the generality of the foregoing:

(i) All documents and instruments necessary to establish, perfect, and maintain the rights of the Seller in the Transferred IP have been validly executed, delivered, and filed in a timely manner with the appropriate Governmental Body.

(ii) Each Person who is or was involved in the creation or development of any Transferred Product or Transferred IP, including but not limited to any Person who is or was an employee or contractor of the Seller, has signed a valid, enforceable agreement containing an assignment of Intellectual Property Rights pertaining to such Transferred Product or Transferred IP to the Seller and confidentiality provisions protecting the Transferred IP.

(iii) The Seller is not bound by, and no Transferred IP is subject to any Contract containing any covenant or other provision that limits or restricts the ability of the Seller to use, exploit, assert, or enforce any Transferred IP.

(iv) The Seller has taken reasonable measures to maintain the confidentiality of and otherwise protect and enforce their rights in all proprietary information pertaining to the Transferred IP.

(v) The Transferred IP constitutes, and, immediately after the Closing the Purchaser will have, all Intellectual Property Rights used in the conduct of the Business as was previously conducted by the Seller.

(g) All issued Patent Rights included in the Transferred IP are subsisting, and, to the Knowledge of the Seller, all such issued Patent Rights are valid and enforceable. All other Transferred IP is subsisting, and, to the Knowledge of the Seller, such other Transferred IP is valid and enforceable. Without limiting the generality of the foregoing:

(i) Each item of Transferred IP that is Registered IP is in compliance with all Legal Requirements and all filings, payments, and other actions required to be made or taken to maintain such item of Transferred IP in full force and effect have been made by the applicable deadline.

(ii) No interference, opposition, reissue, reexamination, or other Proceeding is or has been pending or, to the Knowledge of the Seller, threatened, in which the scope, validity, or

enforceability of any Transferred IP is being, has been, or could reasonably be expected to be contested or challenged.

(h) To the Knowledge of the Seller, no Person has infringed, misappropriated, or otherwise violated, and no Person is currently infringing, misappropriating, or otherwise violating, any Transferred IP.

(i) To the Knowledge of the Seller, the Seller has never infringed (directly, contributorily, by inducement, or otherwise), misappropriated, or otherwise violated or made unlawful use of any Intellectual Property Right of any other Person or engaged in unfair competition. The development, use or sale of the [**] Product or the sIVIG Product (each as defined in Exhibit F hereto) are not covered or claimed by any issued and in force patent that is not owned or controlled by the Seller through the Transferred IP. Notwithstanding any other provision of this Agreement, the Purchaser acknowledges and agrees that the Seller will not be liable to the Purchaser or to any Purchaser Indemnitees for any third-party claims related to any of the patents or patent applications identified in Part 2.4(i) of the Disclosure Schedule or any domestic or foreign counterparts of such patents or patent applications.

(j) There are no pending, nor has there been any written notice of any, threatened actions, suits, proceedings claims or allegations by Persons that the Seller is or will be infringing, violating or unlawfully using any Intellectual Property Rights of any other Person. Without limiting the generality of the foregoing:

(i) No infringement, misappropriation, or similar claim or Proceeding involving or relating to any Transferred IP or any Transferred Product is pending or threatened against the Seller or, to the Knowledge of the Seller, against any other Person who is or may be entitled to be indemnified, defended, held harmless, or reimbursed by the Seller with respect to such claim or Proceeding. The Seller has never received any notice or other communication (in writing or otherwise) relating to any actual, alleged, or suspected infringement, misappropriation, or violation by the Seller, any of its employees or agents, or any Transferred IP or Transferred Product of any Intellectual Property Rights of another Person, including any letter or other communication suggesting or offering that the Seller obtain a license to any Intellectual Property Right of another Person.

(ii) No claim or Proceeding involving any Intellectual Property or Intellectual Property Right licensed to the Seller in connection with the Business or any of the Transferred Assets is pending or has been threatened.

2.5 Contracts.

(a) Part 1.1(c) of the Disclosure Schedule identifies each Transferred Contract. The Seller has made available to the Purchaser accurate and complete copies of all Seller Contracts.

(b) With respect to each of the Contracts identified in Part 1.1(c) of the Disclosure Schedule, except as disclosed in Section 2.5 of the Disclosure Schedule: (i) the Seller has not (and, to the Knowledge of the Seller, no other Person has) violated or breached, or declared or committed any default under, any such Contract; (ii) no event has occurred, and no circumstance or condition exists, that would (with or without notice or lapse of time) result in a violation, breach or default by the Seller (or, to the Knowledge of the Seller, by any other Person) of or under any of the provisions of any such Contract; (iii) the Seller has not received any notice or other communication (in writing or otherwise) regarding any actual or alleged violation or breach of, or default under, any such Contract; and (iv) the Seller has not waived any material right under any such Contract.

2.6 Title to Transferred Assets. The Seller owns, and has good and valid title to all of the Transferred Assets, free and clear of any Encumbrances.

2.7 Tax Matters . All Taxes required to have been paid, or claimed by any Governmental Body to be payable, by the Seller have been duly paid in full on a timely basis. No claim or other Proceeding is pending or, to the Knowledge of the Seller, has been threatened in respect of any Tax. There are no unsatisfied Liabilities for Taxes, whether with respect to any notice of deficiency or similar document received by or on behalf of the Seller or otherwise, except Liabilities for Taxes being contested in good faith by appropriate proceedings or Taxes not yet due and payable. The Seller has not been informed in writing that any company return relating to Taxes is being audited by any Governmental Body.

2.8 Proceedings; Orders . There is no pending Proceeding against or involving the Seller, and no Person has threatened to commence any Proceeding against or involving the Seller. There is no Order to which any of the Transferred Assets is subject. To the Knowledge of the Seller, there is no proposed Order that, if issued or otherwise put into effect: (i) would have an adverse effect on any of the Transferred Assets or on the ability of the Seller to comply with or perform any covenant or obligation under any of the Transactional Agreements; or (ii) would have the effect of preventing, delaying, making illegal or otherwise interfering with any of the Transactions. To Seller's Knowledge, no event has occurred, and no claim, dispute or other condition or circumstance exists, that would reasonably be expected to give rise to or serve as a basis for the commencement of any such Legal Proceeding.

2.9 Compliance with Laws; Regulatory Matters.

(a) The Seller has complied in all material respects with, is not in violation of, and has not received any notices of violation with respect to, any Legal Requirements.

(b) The Seller has made available to the Purchaser all information and data known to the Seller relating to the safety, efficacy or toxicity of any Product.

2.10 Authority; Binding Nature of Agreements . The Seller has the corporate right, power and authority to enter into and to perform its obligations under each of the Transactional Agreements to which it is or may become a party (the "**Seller Transactional Agreements**"); and the execution, delivery and performance by the Seller of the Seller Transactional Agreements have been duly authorized by all necessary action on the part of the Seller and its managers and members. The Seller Transactional Agreements constitute the legal, valid and binding obligations of the Seller, enforceable against the Seller in accordance with their terms, subject to: (i) laws of general application relating to bankruptcy, insolvency and the relief of debtors; and (ii) general principles of equity (the "**Enforceability Exceptions**"). The affirmative vote of the holders of at least sixty percent (60%) of the outstanding Series A Preferred Stock of the Seller are the only votes of the equity holders of the Seller necessary to adopt this Agreement and approve the Transactions.

2.11 Non-Contravention; Consents. The execution and delivery by the Seller of any of the Transactional Agreements, or the consummation or performance by the Seller of any of the Transactions, will not (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of: (i) any of the provisions of the organizational documents of the Seller; or (ii) any resolution adopted by the board of directors or stockholders of the Seller;

(b) contravene, conflict with or result in a violation of any Legal Requirement or any Order to which the Seller or any of the Transferred Assets, is subject;

(c) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Governmental Body the right to revoke, withdraw, suspend, cancel, terminate or modify, any Governmental Authorization that relates to the Transferred Assets;

(d) result in the imposition or creation of any Encumbrance upon or with respect to any Transferred Asset; or

(e) contravene, conflict with or result in a violation or breach of, or result in a default under, any provision of any material Contract to which the Seller is a party or by which the Seller (or any of the Transferred Assets) are bound, or give any Person the right to: (i) declare a default or exercise any remedy under any such Contract; (ii) accelerate the maturity or performance of any such Contract; or (iii) cancel, terminate or modify any such Contract.

Except for any such filings, notices or Consents that have been made or obtained prior to the date of this Agreement, all of which are identified in Section 1.7 of this Agreement, the Seller was not, is not nor will be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with the execution and delivery by the Seller of any of the Transactional Agreements or the consummation or performance by the Seller of any of the Transactions.

2.12 Related Party Transactions. Except as set forth in Part 2.12 of the Disclosure Schedule: (a) no Related Party has, and no Related Party has had, any interest in any material asset used in or otherwise relating to the Business; (b) no Related Party is, or has been, indebted to the Seller (other than for ordinary travel advances); (c) no Related Party has entered into, or has had any financial interest in, any material Contract, transaction or business dealing or involving the Seller; (d) to the Knowledge of the Seller, no Related Party is competing, or has at any time competed, with the Seller; and (e) no Related Party has any claim or right against the Seller (other than rights as an equity holder or licensor or rights to receive compensation for services performed as an employee of the Seller or rights to receive compensation for services performed as a consultant to the Seller, other rights arising in the ordinary course of employment or other rights arising in the ordinary course of consulting).

2.13 No Subsidies. The Seller does not possess (or has ever possessed) or have any rights or interests with respect to (or has ever had any rights or interests with respect to) any grants, incentives or subsidies from any Governmental Body.

2.14 Environmental Matters. The Seller is in material compliance with, and is not in material violation of, and has not received any written notice alleging any material violation by it with respect to any applicable Environmental Law.

2.15 Employees and Employee Benefits. The Seller has complied with all federal, state and local laws relating to the hiring and classification of employees and independent contractors and the employment of labor, including provisions thereof relating to wages, hours, equal opportunity, collective bargaining and the payment of social security and other Taxes. The Seller is not delinquent in payments to any of its employees or independent contractors for any wages, salaries, commissions, bonuses or other direct compensation for any services performed by them or amounts required to be reimbursed to such employees or independent contractors and upon any termination of the employment of any such employees or any termination of status of any independent contractor.

2.16 Brokers. The Seller has not agreed or become obligated to pay, and the Seller has not taken any action that would reasonably be expected to result in any Person claiming to be entitled to receive, any brokerage commission, finder's fee or similar commission or fee in connection with any of the Transactions.

2.17 Full Disclosure. Neither this Agreement nor the Disclosure Schedule contains any untrue statement of material fact; and neither this Agreement nor the Disclosure Schedule omits to state any material fact necessary to make any of the representations, warranties or other statements or information contained therein, in light of the circumstances in which it was made, not misleading. All of the information set forth in the Disclosure Schedule is accurate and complete in all material respects.

3. REPRESENTATIONS AND WARRANTIES OF THE PURCHASER.

The Purchaser represents and warrants, to and for the benefit of the Seller, as follows:

3.1 Due Organization. The Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Purchaser has the power and authority to carry on its business as now being conducted by the Purchaser.

3.2 Authority; Binding Nature of Agreements. The Purchaser has the corporate right, power and authority to enter into and to perform its respective obligations under each Transactional Agreement to which it is or may become a party, and the execution and delivery by the Purchaser of each Transactional Agreement to which the Purchaser is or may become a party has been duly authorized by all necessary action on the part of the Purchaser and its respective boards of directors. This Agreement and each other Transactional Agreement to which the Purchaser is a party constitutes the legal, valid and binding obligation of the Purchaser enforceable against the Purchaser in accordance with its terms, subject to the Enforceability Exceptions.

3.3 Non-Contravention; Consents. Neither the execution and delivery by the Purchaser of any of the Transactional Agreements, nor the consummation or performance by the Purchaser of any of the Transactions, will (with or without notice or lapse of time):

(a) contravene, conflict with or result in a violation of: (i) any of the provisions of the certificate of incorporation or bylaws of the Purchaser; or (ii) any resolution adopted by the stockholders, board of directors or any committee of the board of directors of the Purchaser; or

(b) contravene, conflict with or result in a violation of any Legal Requirement or any Order to which the Purchaser is subject.

The Purchaser is not nor will be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with the execution and delivery by the Purchaser of any of the Transactional Agreements or the consummation or performance by the Purchaser of any of the Transactions.

3.4 Brokers. The Purchaser has not agreed or become obligated to pay, and the Purchaser has not taken any action that would reasonably be expected to result in any Person claiming to be entitled to receive, any brokerage commission, finder's fee or similar commission or fee in connection with any of the Transactions.

4. INDEMNIFICATION, ETC .

4.1 Survival of Representations and Warranties .

(a) Subject to Section 4.1(b), the representations and warranties of the Seller and the Purchaser set forth in this Agreement shall survive the Closing and the consummation of the transactions contemplated hereby and continue until the date twenty-four (24) months after the Closing Date, at which time they shall expire; *provided, however*, that the representations and warranties of the Seller set forth in

Sections 2.1(a), 2.4, 2.6, 2.10 and 2.16 and the representations and warranties of the Purchaser set forth in Sections 3.1, 3.2 and 3.4 shall terminate upon the expiration of the relevant statute of limitations, taking into account extensions thereof; *provided further*, that if a Notice of Claim (as defined on Schedule 4.4) relating to any representation or warranty set forth in Section 2 or Section 3 is given to the Seller or to the Purchaser, as the case may be, on or prior to the applicable expiration date of such representation or warranty, then, notwithstanding anything to the contrary contained in this Section 4.1(a), such representation or warranty shall not so expire, but rather shall remain in full force and effect until such time as each and every Claim that is based upon, or that relates to, any breach of such representation or warranty has been fully and finally resolved.

(b) Notwithstanding anything to the contrary contained in Section 4.1(a), the limitations set forth in Section 4.1(a) shall not apply in the case of claims based upon intentional misrepresentation or fraud.

(c) The representations, warranties, covenants and obligations of the Seller and the Purchaser and the rights and remedies that may be exercised by the Indemnitees, shall not be limited or otherwise affected by or as a result of any information furnished to, or any investigation made by or any knowledge of, any of the Indemnitees or any of their Representatives.

(d) For purposes of this Agreement, each statement or other item of information set forth in the Disclosure Schedule shall be deemed to be a representation and warranty made by the Seller in this Agreement.

4.2 Indemnification .

(a) Subject to the terms and conditions of this Section 4, from and after the Closing, the Seller shall indemnify the Purchaser Indemnitees in respect of, and hold the Purchaser Indemnitees harmless against, and compensate and reimburse each of the Purchaser Indemnitees for, all Damages incurred or suffered by the Purchaser Indemnitees resulting from or constituting:

(i) any breach of a representation or warranty of the Seller contained in this Agreement (without giving effect to any materiality or similar qualification limiting the scope of such representation or warranty);

(ii) any failure by the Seller to perform any covenant or agreement contained in this Agreement or any Ancillary Agreement;

(iii) any Liability of the Seller, other than the Assumed Liabilities;

(iv) any Claim by any stockholder or creditor of Seller against the Purchaser relating to this Agreement or any Transactional Agreements and the Transactions consummated hereby or thereby; or

(v) any Proceeding relating to any breach, alleged breach, Liability or matter of the type referred to in clause "(i)," clause "(ii)," clause "(iii)," or clause "(iv)" (including any Proceeding commenced by any Purchaser Indemnitee for the purpose of enforcing any of its rights under this Section 4).

(b) Subject to the terms and conditions of this Section 4, from and after the Closing, the Purchaser shall indemnify the Seller Indemnitees in respect of, and hold the Seller Indemnitees

harmless against, any and all Damages incurred or suffered by the Seller Indemnitees resulting from or constituting:

- (i) any breach of a representation or warranty of the Purchaser contained in this Agreement;
- (ii) any failure by the Purchaser to perform any covenant or agreement contained in this Agreement or any Ancillary Agreement;
- (iii) any Assumed Liabilities;
- (iv) any Claim by any stockholder or creditor of the Purchaser against the Seller relating to this Agreement or any Transactional Agreements and the Transactions consummated hereby or thereby; or
- (v) any Proceeding relating to any breach, alleged breach, Liability or matter of the type referred to in clause “(i),” clause “(ii),” clause “(iii),” or clause “(iv)” (including any Proceeding commenced by any Seller Indemnitee for the purpose of enforcing any of its rights under this Section 4).

(c) Notwithstanding anything to the contrary contained in this Agreement, the following limitations shall apply to indemnification claims under this Agreement:

- (i) the Seller shall be liable with respect to claims under Section 4.2(a)(i) for only that portion of the aggregate Damages related to such claims, considered together, which exceed \$50,000;
- (ii) the aggregate liability of the Seller for all Damages under Section 4.2(a)(i) shall not exceed the Indemnification Cap;
- (iii) the Purchaser shall be liable with respect to claims under Section 4.2(b)(i) for only that portion of the aggregate Damages related to such claims, considered together, which exceed \$50,000; and
- (iv) the aggregate liability of the Purchaser for all Damages under Section 4.2(b)(i) shall not exceed the Indemnification Cap;

provided, however, that the limitations set forth in Sections 4.2(c)(i) and (ii) shall not apply to claims of breach of the representations or warranties of the Seller under Sections 2.1(a), 2.6, 2.10 and 2.16, and the limitations set forth in Sections 4.2(c)(iii) and (iv) shall not apply to claims of breach of the representations or warranties of the Purchaser under Sections 3.1, 3.2 and 3.4.

(d) The limitations set forth in Section 4.2(c) shall not apply to any claim by an Indemnitee for intentional misrepresentation or fraud. Setoff against the Milestone Payments shall be the Purchaser Indemnitees’ sole and exclusive remedy for monetary Damages with respect to an inaccuracy in or breach of the representations and warranties of the Seller contained in this Agreement. Notwithstanding anything to the contrary contained in this Agreement, nothing in this Agreement shall limit or restrict in any manner whatsoever any remedy (under this Agreement, under applicable law, in equity or otherwise) of any Purchaser Indemnitee or Seller Indemnitee against any Person relating to or arising from any intentional misrepresentation or fraud.

4.3 Defense of Third-Party Claims. All claims for indemnification made under this Agreement resulting from, related to or arising out of a third-party claim against an Indemnified Party shall be made in accordance with the following procedures. An Indemnified Party shall give prompt written notification to the Indemnifying Party of the commencement of any action, suit or proceeding relating to a third-party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a third party. Such notification shall include a description in reasonable detail (to the extent known by the Indemnified Party) of the facts constituting the basis for such third-party claim and the amount of the Damages claimed. Within 15 days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim at its sole cost and expense with counsel reasonably satisfactory to the Indemnified Party; *provided that* (i) the Indemnifying Party may only assume control of such defense if it acknowledges in writing to the Indemnified Party that any Damages or other Liabilities that may be assessed against the Indemnified Party in connection with such third-party claim constitute Damages for which the Indemnified Party shall be indemnified pursuant to this Section 4 and (ii) the Indemnifying Party may not assume control of the defense of a third-party claim involving criminal liability or in which equitable relief is sought against the Indemnified Party. If the Indemnifying Party does not, or is not permitted under the terms hereof to, so assume control of such defense, the Indemnified Party shall control such defense. The Party not controlling such defense may participate therein at its own expense; provided that if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith shall be considered “Damages” for purposes of this Agreement; provided, however, that in no event shall the Indemnifying Party be responsible for the fees and expenses of more than one counsel for all Indemnified Parties. The party controlling such defense shall keep the other party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other party with respect thereto. The Indemnified Party shall not agree to any settlement of, or the entry into judgment arising from, any such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, conditioned or delayed. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim that does not include a complete release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld, conditioned or delayed.

4.4 Claim Procedure. Any claim for indemnification, compensation or reimbursement pursuant to this Section 4 (and, at the option of any Indemnitee, any other claim for a monetary remedy, such as in the case of a claim based upon intentional misrepresentation or fraud, relating to this Agreement) shall be brought and resolved exclusively in accordance with Schedule 4.4.

5. CERTAIN POST-CLOSING AND OTHER COVENANTS .

5.1 Achievement of Milestones. Following the Closing, the Purchaser shall use Commercially Reasonable Efforts to achieve the Milestones.

5.2 Further Actions. From and after the date of this Agreement for a period of ninety (90) days, the Seller shall cooperate with the Purchaser and its respective Representatives, and shall execute and deliver such documents and take such other actions as the Purchaser may reasonably request to engage John W. Ripple to act on Seller’s behalf; *provided, however*, that in the event that Mr. Ripple commences employment or consulting with a Person other than the Seller during the period thirty (30) to ninety (90) days following the Closing, the period of cooperation by the Seller set forth in this Section 5.2 shall cease on the date of such commencement of employment or consulting. To the extent that the parties

hereto have been unable to obtain any Consent necessary be obtained for the transfer to the Purchaser of any of the Transferred Assets by the date of this Agreement: (a) such Transferred Asset (a “**Specified Asset**”) shall not be assigned or transferred to Purchaser until such time as such Consent is obtained, without any reduction in the Purchase Price under Section 1.3 and (b) the Seller shall use its reasonable efforts to obtain such Consent as promptly as practicable thereafter, provided that that the Seller shall not be required to make any payments or agree to any material undertakings in connection therewith. Until such Consent is obtained, Seller shall cooperate, and shall use its reasonable efforts to cause its Representatives to cooperate, with the Purchaser in any lawful arrangement designed to provide Purchaser with the benefits of such Specified Assets at no cost to the Purchaser in excess of the cost the Purchaser would have incurred (without modification to the terms of any Contract) if the Consent had been obtained. If a required Consent with respect to a Specified Asset is obtained after the Closing Date, the Specified Asset subject to such Consent shall be deemed to have been assigned and transferred to the Purchaser as of the date such Consent is effective (and all references in Section 1.3(a) to the Closing Date shall be deemed to be the effective date of such Consent with respect to such Specified Asset). The Seller hereby irrevocably nominates, constitutes and appoints the Purchaser as the true and lawful attorney-in-fact of the Seller (with full power of substitution) effective as of the date of this Agreement, and hereby authorizes the Purchaser, in the name of and on behalf of the Seller, to execute, deliver, acknowledge, certify, file and record any document, to institute and prosecute any Proceeding and to take any other action (on or at any time after the date of this Agreement) that the Purchaser may deem appropriate for the purpose of: (i) collecting, asserting, enforcing or perfecting any claim, right or interest of any kind that is included in or relates to any of the Transferred Assets; (ii) defending or compromising any claim or Proceeding relating to any of the Transferred Assets; or (iii) otherwise carrying out or facilitating any of the Transactions. The power of attorney referred to in the preceding sentence is and shall be coupled with an interest and shall be irrevocable, and shall survive the dissolution or insolvency of the Seller.

5.3 Tax Cooperation; Allocation of Taxes .

(a) The Seller and the Purchaser agree to furnish or cause to be furnished to each other, upon request, as promptly as practicable, such information and assistance relating to the Business or the Transferred Assets (including access to books and records) as is reasonably necessary for the filing of all Tax Returns, and the making of any election related to Taxes, the preparation for any audit by any taxing authority, and the prosecution or defense of any claim, suit or proceeding relating to any Tax Return. The Seller shall retain all books and records with respect to Taxes pertaining to the Transferred Assets for a period of at least six years following the Closing.

(b) All real property taxes, personal property taxes and similar ad valorem obligations levied with respect to the Business or the Transferred Assets for a taxable period that includes (but does not end on) the date of the Closing shall be apportioned between the Seller and the Purchaser as of the Closing based on the number of days of such taxable period ending on the date of the Closing (the “**Pre-Closing Tax Period**”) and the number of days of such taxable period after the date of this Agreement (with respect to any such taxable period, the “**Post-Closing Tax Period**”). The Seller shall be liable for the proportionate amount of such Taxes that is attributable to the Pre-Closing Tax Period, and the Purchaser shall be liable for the proportionate amount of such Taxes that is attributable to the Post-Closing Tax Period. Upon receipt of any bill for real or personal property Taxes relating to the Business or the Transferred Assets, the Seller and the Purchaser, as applicable, shall present a reasonably detailed, written statement to the other setting forth the amount of reimbursement to which each is entitled under this Section 5.3(b) together with such supporting evidence as is reasonably necessary to calculate the proration amount. The proration amount shall be paid by the party owing it to the other within 20 days after delivery of such statement. In the event that either the Seller or the Purchaser shall make any other payment for which it is entitled to reimbursement under this Section 5.3(b), the other party shall make such reimbursement promptly but in no event later than 20 days after the presentation of a reasonably

detailed, written statement setting forth the amount of reimbursement to which the presenting party is entitled along with such supporting evidence as is reasonably necessary to calculate the amount of reimbursement.

5.4 Continuing Access to Information. Following the Closing for a period of ninety (90) days, the Seller shall give the Purchaser and its respective Representatives reasonable access during normal business hours to (and shall allow the Purchaser and its Representatives to make copies of) any books and records relating to the Transferred Assets for any reasonable purpose.

5.5 Publicity. The Seller and the Purchaser agree that, on and at all times after the date of this Agreement: (a) no press release or other publicity concerning any of the Transactions shall be issued or otherwise disseminated by it or on its behalf without the party's prior written consent; and (b) it shall continue to keep the terms of this Agreement and the other Transactional Agreements strictly confidential; *provided, however*, that the Seller and its affiliates may disclose the fact that the Purchaser acquired the Transferred Assets of the Seller, without disclosing the terms of this Agreement; *provided, further*, that the existence and terms of this Agreement and the other Transactional Agreements may be disclosed to the extent required by law or pursuant to rules or regulations of any regulatory authority having jurisdiction over such party, provided that before making such a disclosure, such party first notifies the Purchaser and gives the Purchaser an opportunity to limit such disclosure or seek a protective order and cooperates with the Purchaser as reasonably requested. Notwithstanding the foregoing, the Seller and Purchaser have agreed on language of a press release in substantially the form attached hereto as Exhibit G announcing the transaction.

5.6 Noncompetition . The Seller agrees that from the Closing Date to the third anniversary of the Closing Date, the Seller shall not (a) engage directly or indirectly in Competition in any part of the world; or (b) directly or indirectly be or become an equityholder, owner, co-owner, affiliate, partner, promoter, agent, representative, designer, consultant, advisor or manager of, for or to, or otherwise be or become associated with or acquire or hold any direct or indirect interest in, any person that engages directly or indirectly in Competition anywhere in the world.

5.7 Development Plan . The Purchaser shall deliver an updated Development Plan (as defined in the Rockefeller License Agreement) to The Rockefeller University within forty-five (45) days after the Closing Date.

6. MISCELLANEOUS PROVISIONS .

6.1 Fees and Expenses .

(a) The Seller shall bear and pay all fees, costs and expenses (including fees and expenses of the Seller's legal, accounting, financial and other advisors) that have been incurred or that are in the future incurred by, on behalf of or for the benefit of, the Seller in connection with: (i) the negotiation, preparation and review of any term sheet or similar document relating to any of the Transactions; (ii) the negotiation, preparation and review of this Agreement (including the Disclosure Schedule) and the other Transactional Agreements; (iii) the preparation and submission of any filing or notice required to be made or given in connection with any of the Transactions, and the obtaining of any Consent required to be obtained by the Seller in connection with any of the Transactions; and (iv) the consummation and performance of the Transactions.

(b) The Purchaser shall bear and pay all fees, costs and expenses (including fees and expenses of the Purchaser's legal, accounting, financial and other advisors) that have been incurred or that are in the future incurred by, or on behalf of for the benefit of, the Purchaser in connection with: (i) the

negotiation, preparation and review of any term sheet or similar document relating to any of the Transactions; (ii) the negotiation, preparation and review of this Agreement and the other Transactional Agreements; (iii) the preparation and submission of any filing or notice required to be made or given in connection with any of the Transactions, and the obtaining of any Consent required to be obtained by the Purchaser in connection with any of the Transactions; and (iv) the consummation and performance of the Transactions.

6.2 Attorneys' Fees. If any Proceeding relating to any of the Transactional Agreements or the enforcement of any provision of any of the Transactional Agreements is brought against any party to this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees, costs and disbursements (in addition to any other relief to which the prevailing party may be entitled).

6.3 Notices. Any notice or other communication required or permitted to be delivered to any party under this Agreement shall be in writing and shall be deemed properly delivered, given and received: (a) when delivered by hand; (b) if sent by registered, certified or first class mail, the third business day after being sent; and (c) if sent by overnight delivery via a national courier service, one business day after being sent, in each case to the address or electronic mail address set forth beneath the name of such party below (or to such other address or electronic mail address as such party shall have specified in a written notice given to the other parties hereto):

if to the Purchaser:

Momenta Pharmaceuticals, Inc.
675 W. Kendall St.
Cambridge, MA 02142
Attention: General Counsel

with a copy to:

Cooley LLP
500 Boylston Street
Boston, MA 02116-3736
Attention: Nicole Brookshire

if to the Seller:

Virdante Pharmaceuticals, Inc.
c/o Clarus Ventures
101 Main Street, Suite 1210
Cambridge, MA 02142
Attention: John W. Ripple

with a copy to:

WilmerHale
399 Park Avenue
New York, NY 10022
Attn: Steven D. Singer

6.4 Headings. The bold-faced headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

6.5 Counterparts and Exchanges by Electronic Delivery. This Agreement may be executed in several counterparts, each of which shall constitute an original and all of which, when taken together, shall constitute one agreement. The exchange of a fully executed Agreement (in counterparts or otherwise) by electronic delivery in .pdf format shall be sufficient to bind the parties to the terms and conditions of this Agreement.

6.6 Governing Law; Venue .

(a) This Agreement shall be construed in accordance with, and governed in all respects by, the internal laws of the Commonwealth of Massachusetts (without giving effect to principles of conflicts of laws).

(b) Any Proceeding relating to this Agreement or the enforcement of any provision of this Agreement must be brought or otherwise commenced in any state or federal court located in the County of Suffolk, Massachusetts. Each party to this Agreement:

(i) expressly and irrevocably consents and submits to the jurisdiction of each state and federal court located in the County of Suffolk, Massachusetts (and each appellate court located in the Commonwealth of Massachusetts) in connection with any such Proceeding;

(ii) agrees that each state and federal court located in the County of Suffolk, Massachusetts shall be deemed to be a convenient forum; and

(iii) agrees not to assert (by way of motion, as a defense or otherwise), in any such Proceeding commenced in any state or federal court located in the County of Suffolk, Massachusetts, any claim that such party is not subject personally to the jurisdiction of such court, that such Proceeding has been brought in an inconvenient forum, that the venue of such proceeding is improper or that this Agreement or the subject matter of this Agreement may not be enforced in or by such court.

(c) Notwithstanding the foregoing, the Seller agrees that if any Proceeding is commenced against any Purchaser Indemnitee by any Person in or before any court or other tribunal anywhere in the world, then such Purchaser Indemnitee may proceed against the Seller in or before such court or other tribunal with respect to any indemnification claim or other claim arising from or relating to such Proceeding or any of the matters alleged therein or any of the circumstances giving rise thereto.

6.7 Successors and Assigns; Parties in Interest .

(a) This Agreement shall be binding upon: the Seller and its successors and assigns (if any); the Purchaser and its successors and assigns (if any). This Agreement shall inure to the benefit of: the Seller; the Purchaser; the other Indemnitees; and the respective successors and assigns (if any) of the foregoing.

(b) The Purchaser shall have the right to assign this Agreement to an affiliated company or in connection with the merger, consolidation, sale or transfer of all or substantially all of the business to which this Agreement relates. The Seller shall not be permitted to assign any of its respective rights or delegate any of its respective obligations under this Agreement without the Purchaser's prior written consent other than to a nominee, including but not limited to a liquidating trust, in connection with the wind down or liquidation of the Seller. Any attempted assignment or delegation by the Seller in violation of this Section 6.7(b) shall be null and void.

(c) None of the provisions of this Agreement is intended to provide any rights or remedies to any Person other than the parties to this Agreement and the other Indemnitees (and their respective successors and permitted assigns, if any). Without limiting the generality of the foregoing: (i) no employee of the Seller shall have any rights under this Agreement or under any of the other Transactional Agreements; and (ii) no creditor of the Seller shall have any rights under this Agreement or any of the other Transactional Agreements.

6.8 Remedies Cumulative; Specific Performance. The rights and remedies of the parties hereto shall be cumulative (and not alternative). Each party agrees that: (a) in the event of any breach or threatened breach by the other party of any covenant, obligation or other provision set forth in this Agreement, such party shall be entitled (in addition to any other remedy that may be available to it) to: (i) a decree or order of specific performance or mandamus to enforce the observance and performance of such covenant, obligation or other provision; and (ii) an injunction restraining such breach or threatened breach; and (b) no Person shall be required to provide any bond or other security in connection with any such decree, order or injunction or in connection with any related Proceeding.

6.9 Waiver . No failure on the part of any Person to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any Person in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy. No Person shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such Person; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

6.10 Amendments. This Agreement may not be amended, modified, altered or supplemented other than by means of a written instrument duly executed and delivered on behalf of the parties hereto.

6.11 Severability. In the event that any provision of this Agreement, or the application of any such provision to any Person or set of circumstances, shall be determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to Persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, shall not be impaired or otherwise affected and shall continue to be valid and enforceable to the fullest extent permitted by law.

6.12 Entire Agreement. The Transactional Agreements set forth the entire understanding of the parties relating to the subject matter thereof and supersede all prior agreements and understandings among or between any of the parties relating to the subject matter thereof.

6.13 Disclosure Schedule. The Disclosure Schedule shall be arranged in separate parts corresponding to the numbered and lettered sections contained herein permitting such disclosure, and the information disclosed in any numbered or lettered part shall be deemed to relate to and to qualify other numbered and lettered sections contained herein to the extent it is reasonably apparent on the face of the disclosure that such information is applicable to such other sections.

6.14 Construction .

(a) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and

neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include the masculine and feminine genders.

(b) The parties hereto agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not be applied in the construction or interpretation of this Agreement or to the other Transactional Agreements. Each of the parties hereto acknowledges that he or it has received independent legal advice in connection with the negotiation and execution of this Agreement and the other Transactional Agreements or has determined that such advice is not necessary.

(c) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

(d) Except as otherwise indicated, all references in this Agreement and the Exhibits to this Agreement to “Sections,” “Exhibits” and “Schedules” are intended to refer to Sections of this Agreement, Exhibits to this Agreement and Schedules to this Agreement.

[Remainder of page intentionally left blank]

The parties to this Agreement have caused this Agreement to be executed and delivered as of the date first written above.

MOMENTA PHARMACEUTICALS, INC.,
a Delaware corporation

By: /s/ Craig A. Wheeler
Name: Craig A. Wheeler
Title: President and Chief Executive Officer

VIRDANTE PHARMACEUTICALS, INC. ,
a Delaware corporation

By: /s/ John W. Ripple
Name: John W. Ripple
Title: Chief Executive Officer

ASSET PURCHASE AGREEMENT
SIGNATURE PAGE

EXHIBIT A

CERTAIN DEFINITIONS

For purposes of the Agreement (including this Exhibit A):

Agreement. “Agreement” shall mean the Asset Purchase Agreement to which this Exhibit A is attached (including the Disclosure Schedule), as it may be amended from time to time.

Balance Sheet . “Balance Sheet” shall mean the unaudited balance sheet of the Seller for the six months ended September 30, 2011.

Balance Sheet Date . “Balance Sheet Date” shall mean September 30, 2011.

Books and Records. “Books and Records” means all files, documents, instruments, papers of Seller other than the Transferred Records.

Business. “Business” shall mean the Seller’s research and development business related to the Products.

Claim. “Claim” shall mean and include all past, present and future disputes, claims, controversies, demands, rights, obligations, liabilities, actions and causes of action of every kind and nature, including: (a) any unknown, inchoate, unsuspected or undisclosed claim; and (b) any claim, right or cause of action based upon any breach of any express, implied, oral or written contract or agreement.

Commercially Reasonable Efforts. “Commercially Reasonable Efforts” shall mean with respect to the Purchaser, such efforts that are consistent with the efforts and resources normally used by the Purchaser in the exercise of its reasonable business discretion for a product in the Purchaser’s pipeline of similar market potential at a similar stage in its product life, taking into account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary positions of the Transferred Assets and third parties, the quality of the clinical data and emerging product profile, the regulatory structure involved, the profitability of the Transferred Assets, and other relevant factors, including without limitation, the scientific and development risk of a project or product, the cost of goods, research and development costs, alternative discovery and development opportunities that offer a higher return on investment, and reasonable capital allocation decisions that take into account the best interests of the Purchaser’s stockholders.

Competition. “Competition” shall mean any business or activity involving or relating to in any respect (other than an immaterial respect) any aspect of the engineering, design, development, production, license, manufacture or distribution of a sialylated IVIG or sialylated [**] compound, product, product candidate, cell line or constituent thereto.

Consent. “Consent” shall mean any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

Contract. “Contract” shall mean any written or oral agreement, contract, arrangement, instrument, note, guaranty, indemnity, deed, assignment, power of attorney, certificate, purchase order, work order, insurance policy, benefit plan, commitment or undertaking of any nature.

Damages. “Damages” shall include any loss, damage, injury, Liability, Claim, settlement, judgment, award, fine, penalty, Tax, fee (including any legal fee, expert fee, accounting fee or advisory fee), charge, cost (including any cost of investigation) or expense of any nature.

Disclosure Schedule. “Disclosure Schedule” shall mean the schedule (dated as of the date of the Agreement) delivered to the Purchaser on behalf of the Seller.

Encumbrance. “Encumbrance” shall mean any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, claim, right of possession, lease, tenancy, license, encroachment, Order, option, right of first refusal, preemptive right, community property interest, defect, impairment, imperfection of title (including any restriction on the transfer of any asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

Entity. “Entity” shall mean any corporation (including any non-profit corporation), general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, cooperative, foundation, society, political party, union, company (including any limited liability company or joint stock company), firm or other enterprise, association, organization or entity.

Environment. “Environment” includes: (a) any and all buildings, structures, fixtures, fittings, appurtenances, pipes, conduits, valves, tanks, vessels and containers whether above or below ground level; and (b) ambient air, land surface, sub-surface strata, soil, surface water, ground water, river sediment, marshes, wet lands, flora and fauna.

Environmental Law . “Environmental Law” shall mean: (a) the common law; and (b) all Legal Requirements, by-laws, orders, instruments, directives, decisions, injunctions and judgments of any government, local government, international, supranational, executive, administrative, judicial or regulatory authority or agency and all approved codes of practice (whether voluntary or compulsory) relating to the protection of the Environment or of human health or safety or welfare or to the manufacture, formulation, processing, treatment, storage, containment, labeling, handling, transportation, distribution, recycling, reuse, release, disposal, removal, remediation, abatement or clean-up of any contaminant and any amendment thereto and any and all regulations, orders and notices made or served thereunder or pursuant thereto).

Excluded Assets . “Excluded Assets” shall mean all assets of the Seller other than those specifically listed or described in the definition of Transferred Assets. Without limitation of the foregoing, the Excluded Assets shall include: (a) all cash and cash equivalents or similar investments, bank accounts, commercial paper, certificates of deposit, Treasury bills and other marketable securities; (b) all rights which accrue or will accrue to the benefit of the Seller under this Agreement or the Transactional Agreements; (c) the Seller’s corporate name, Viridante Pharmaceuticals; and (d) the Books and Records of the Seller.

Environmental Licenses. “Environmental License” shall mean any Consent or Governmental Authorization required by or pursuant to any applicable Environmental Laws.

Financial Statements . “Financial Statements” shall mean the Seller’s audited balance sheets and related audited statements of income as of December 31, 2008 and 2009 and unaudited balance sheet and related unaudited statement of income as of December 31, 2010.

Governmental Authorization. “Governmental Authorization” shall mean any: (a) permit, license, certificate, franchise, concession, approval, consent, ratification, permission, clearance, confirmation, endorsement, waiver, certification, designation, rating, registration, qualification or

authorization (including all pending applications therefore or renewals thereof) issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Legal Requirement; or (b) right under any Contract with any Governmental Body.

Governmental Body. “Governmental Body” shall mean any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or Entity and any court or other tribunal); (d) multi-national organization or body; or (e) individual, Entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

Indemnification Cap. “Indemnification Cap” shall mean the amount equal to twenty percent (20%) of each Milestone Payment not yet paid by the Purchaser to the Seller pursuant to Section 1.3 as of the date on which the indemnifiable loss was incurred (it being agreed that the Seller shall always be entitled to receive eighty percent (80%) of each such Milestone Payment).

Intellectual Property. “Intellectual Property” shall mean algorithms, apparatus, databases, data collections, diagrams, formulae, inventions (whether or not patentable), know-how, logos, marks, methods, processes, proprietary information, protocols, schematics, specifications, techniques, user interfaces, URLs, web sites, works of authorship and other forms of technology (whether or not embodied in any tangible form and including all tangible embodiments of the foregoing, such as instruction manuals, laboratory notebooks, prototypes, samples, studies and summaries).

Intellectual Property Rights. “Intellectual Property Rights” shall mean all past, present, and future rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (a) rights associated with works of authorship, including exclusive exploitation rights, copyrights, moral rights and mask works; (b) trademark and trade name rights and similar rights; (c) trade secret rights; (d) patent and industrial property rights; (e) other proprietary rights in Intellectual Property; and (f) rights in or relating to registrations, renewals, extensions, combinations, divisions, and reissues of, and applications for, any of the rights referred to in clauses “(a)” through “(e)” above.

Knowledge. Knowledge shall mean actual knowledge as of the date hereof of the Seller’s Chief Executive Officer, John W. Ripple, together with such knowledge that such individual would be expected to have discovered after reasonable investigation concerning the existence of the fact or matter in question.

Legal Requirement. “Legal Requirement” shall mean any federal, state, local, municipal, foreign or other law, statute, legislation, constitution, principle of common law, resolution, ordinance, code, edict, decree, proclamation, treaty, convention, rule, regulation, ruling, directive, pronouncement, requirement, specification, determination, decision, guideline, opinion or interpretation issued, enacted, adopted, passed, approved, promulgated, made, implemented or otherwise put into effect by or under the authority of any Governmental Body.

Liability. “Liability” shall mean any debt, obligation, duty or liability of any nature (including any unknown, undisclosed, unmatured, unaccrued, unasserted, contingent, indirect, conditional, implied, vicarious, derivative, joint, several or secondary liability), regardless of whether such debt, obligation, duty or liability would be required to be disclosed on a balance sheet prepared in accordance with generally accepted accounting principles in the United States and regardless of whether such debt, obligation, duty or liability is immediately due and payable.

Material Adverse Effect . “Material Adverse Effect” shall mean any material adverse change, event, circumstance or development with respect to, or material adverse effect on, (i) the assets, liabilities, capitalization, financial condition or results of operations of the Seller or (ii) the ability of the Purchaser to operate the business of the Seller immediately after the Closing.

Order. “Order” shall mean any: (a) order, judgment, injunction, edict, decree, ruling, pronouncement, determination, decision, opinion, verdict, sentence, subpoena, writ or award issued, made, entered, rendered or otherwise put into effect by or under the authority of any court, administrative agency or other Governmental Body or any arbitrator or arbitration panel; or (b) Contract with any Governmental Body entered into in connection with any Proceeding.

Patent Rights . “Patent Rights” shall mean (a) any patents, patent applications, provisional patent applications and similar instruments; and (b) to the extent related thereto or derived therefrom, any and all substitutions, reissues, renewals, extensions, utility models, reexaminations, patents of addition, supplementary protection certificates, inventors’ certificates, extensions, requests for continued examinations, designs, divisions, re-filings, continuations and continuations-in-part thereof, or the like and any foreign equivalents thereof (including certificates of invention and any applications therefor) and all documentation associated therewith.

Person. “Person” shall mean any individual, Entity or Governmental Body.

Proceeding. “Proceeding” shall mean any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding and any informal proceeding), prosecution, contest, hearing, inquiry, inquest, audit, examination or investigation commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Body or any arbitrator or arbitration panel.

Product . “Product” shall mean any and all compounds, products, product candidates, cell line or constituent thereof engineered, designed, developed, licensed or manufactured by, or on behalf of, the Seller, including but not limited to any proposed products which have previously been or are currently under pre-clinical development as of the date of this Agreement.

Product Materials. “Product Materials” shall mean (a) all inventory of Product owned or controlled by Seller as of the Closing and (b) all samples or materials owned or controlled by Seller as of the Closing derived from or used in research studies of or for a Product.

Purchaser Indemnitees. “Purchaser Indemnitees” shall mean the following Persons: (a) the Purchaser; (b) the current and future affiliates of the Purchaser; (c) the respective Representatives of each the Persons referred to in clauses (a) and (b) above; the respective successors and assigns of the Persons referred to in clauses (a), (b) and (c).

Registered IP . “Registered IP” shall mean all Intellectual Property Rights that are registered, filed or issued under the authority of, with or by any Governmental Body, including all patents,

Related Party . “Related Party” shall mean: (a) each holder of equity interests of the Seller; (b) each individual who is an officer or director of the Seller; (c) each member of the immediate family of each of the individuals referred to in clauses “(a),” and “(b)” above; and (d) any trust or other Entity in which any one of the Persons referred to in clauses “(a),” “(b)” and “(c)” above holds (or in which more than one of such Persons collectively hold), beneficially or otherwise, a material voting, proprietary or equity interest.

Representatives. "Representatives" shall mean officers, directors, managers, employees, agents, attorneys, accountants and advisors.

Rockefeller License Agreement. "Rockefeller License Agreement" shall mean the Second Amended and Restated License Agreement, effective May 7, 2010, by and between the Seller and The Rockefeller University.

Seller Contract. "Seller Contract" shall mean any Contract: (a) to which the Seller is a party; (b) by which the Seller or any of its assets is or may become bound or under which the Seller has, or may become subject to, any obligation; or (c) under which the Seller has or may acquire any right or interest.

Seller Indemnitees. "Seller Indemnitees" shall mean the following Persons: (a) the Seller; (b) the current affiliates of the Seller; (c) the respective Representatives of each the Persons referred to in clauses (a) and (b) above; the respective successors and assigns of the Persons referred to in clauses (a), (b) and (c) and collectively with the Purchaser Indemnitees (the "**Indemnitees**").

Tax. "Tax" shall mean any tax (including any income tax, franchise tax, capital gains tax, estimated tax, gross receipts tax, value-added tax, surtax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, occupation tax, inventory tax, occupancy tax, withholding tax or payroll tax), levy, assessment, tariff, impost, imposition, toll, duty (including any customs duty), deficiency or fee, and any related charge or amount in the nature of a tax (including any fine, penalty or interest), that is or has been (a) imposed, assessed or collected by or under the authority of any Governmental Body, or (b) payable pursuant to any tax-sharing agreement or similar Contract.

Tax Return. "Tax Return" shall mean any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information that is, has been or may be in the future be filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Legal Requirement relating to any Tax.

Transactional Agreements. "Transactional Agreements" shall mean: (a) the Agreement; (b) the Bill of Sale and Assignment Agreement; (c) the Assignment and Assumption Agreement; and (f) all bills of sale, assignments and other agreements delivered or to be delivered in connection with the transactions contemplated by the Agreement.

Transactions. "Transactions" shall mean: (a) the execution and delivery of the Transactional Agreements; and (b) all of the transactions contemplated by the Transactional Agreements, including: (i) the sale of the Transferred Assets by the Seller to the Purchaser in accordance with the Agreement; and (ii) the performance by the Seller and the Purchaser of their respective obligations under the Transactional Agreements, and the exercise by the Seller and the Purchaser of their respective rights under the Transactional Agreements.

A-5

EXHIBIT B

FORM OF BILL OF SALE AND ASSIGNMENT AGREEMENT

THIS BILL OF SALE AND ASSIGNMENT is made as of December 2, 2011, by **VIRDANTE PHARMACEUTICALS, INC.**, a Delaware corporation (the "**Seller**"), for the benefit of **MOMENTA PHARMACEUTICALS, INC.**, a Delaware corporation (the "**Buyer**"). Capitalized terms used but not defined in this Bill of Sale and Assignment shall have the meanings given to them in the Purchase Agreement (as defined below).

WITNESSETH:

WHEREAS, pursuant and subject to the terms and conditions of an Asset Purchase Agreement of even date herewith, by and between the Seller and the Buyer (the "**Purchase Agreement**"), the Seller is causing the Purchased Assets to be sold, assigned, transferred, conveyed and delivered to the Buyer.

WHEREAS, by this instrument, the Seller is vesting in the Buyer all of the Seller's right, title and interest in and to the Purchased Assets, free of any Encumbrances other than Permitted Encumbrances.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Seller hereby sells, assigns, transfers, conveys and delivers to the Buyer all of the Seller's right, title and interest in and to all the Purchased Assets, free of any Encumbrances other than Permitted Encumbrances.

Nothing contained in this Bill of Sale and Assignment is intended to provide any rights to the Buyer or the Seller beyond those rights expressly provided to the Buyer or the Seller in the Purchase Agreement. Nothing contained in this Bill of Sale and Assignment is intended to impose any obligations or liabilities on the Buyer or the Seller beyond those obligations and liabilities expressly imposed on the Buyer or the Seller in the Purchase Agreement. Nothing contained in this Bill of Sale and Assignment is intended to limit any of the rights or remedies available to the Buyer or the Seller under the Purchase Agreement. Nothing contained in this Bill of Sale and Assignment shall be deemed to alter or amend the terms and provisions of the Purchase Agreement, and in the event of any conflict between the terms and provisions of this Bill of Sale and Assignment and the Purchase Agreement, the terms and provisions of the Purchase Agreement shall be deemed to govern and be controlling.

This Bill of Sale and Assignment shall be construed in accordance with, and governed in all respects by, the internal laws of the Commonwealth of Massachusetts (without giving effect to principles of conflicts of laws).

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF , the Seller has caused this Bill of Sale and Assignment to be executed and delivered as of the date first written above.

VIRDANTE PHARMACEUTICALS, INC. ,
a Delaware corporation

By: _____
Name: John W. Ripple
Title: Chief Executive Officer

AGREED AND ACCEPTED:

MOMENTA PHARMACEUTICALS, INC. ,
a Delaware corporation

By: _____
Name: Craig A. Wheeler
Title: President and Chief Executive Officer

[*Signature Page to Bill of Sale and Assignment*]

EXHIBIT C

FORM OF CONSENT OF THE ROCKEFELLER UNIVERSITY

VIRDANTE PHARMACEUTICALS, INC.

101 Main Street, Suite 1210
Cambridge, MA 02142

November 30, 2011

Via E-mail and Federal Express

Kathleen A. Denis, Ph.D.
Associate Vice President
Office of Technology Transfer
The Rockefeller University
1230 York Avenue, Box 138
New York, NY 10065

RE: Important Confidential Matter

Dear Kathleen:

In connection with the Second Amended and Restated License Agreement effective May 7, 2010 by and between Virdante Pharmaceuticals, Inc. (“Virdante”) and The Rockefeller University (“Rockefeller”) (the “License Agreement”), Virdante is writing to provide information to Rockefeller regarding an important confidential matter and requests that Rockefeller and Buyer (as defined below) agree to the terms as set forth herein. As you know, earlier this year, Virdante commenced efforts to seek a strategic acquirer or licensor (the “Strategic Process”) for technology licensed to Virdante from Rockefeller under the License Agreement and that was the subject of sponsored research under the Sponsored Research Agreement dated May 7, 2007, as amended, by and between Virdante and Rockefeller (the “Sponsored Research Agreement”).

In connection with the Strategic Process, I am pleased to report that Virdante is in discussions with Momenta Pharmaceuticals, Inc. (“Buyer”) regarding a possible transaction in which Buyer proposes to acquire certain assets of Virdante by means of an asset purchase agreement (the “Transaction”). Subject to and upon the closing of the Transaction, Virdante would assign, and Buyer would assume, the License Agreement as well as the Non-Exclusive Research and Development Use License Agreement, dated February 10, 2010 by and between Virdante and Rockefeller and the Letter Agreement by and between Virdante and Rockefeller, dated November 29, 2011 (the “Ancillary Agreements”).

Subject to obtaining your consent and upon the closing of the Transaction, Virdante will assign to the Buyer all of Virdante’s rights under the License Agreement and Ancillary Agreements. In addition, subject to obtaining your consent and upon the closing of the Transaction, the Buyer will assume all of Virdante’s obligations pursuant to the License Agreement and the Ancillary Agreements.

Accordingly, Virdante, Rockefeller and Buyer hereby agree to the terms and conditions set forth below:

- 1. Buyer Representations:** Buyer represents to Rockefeller that it accepts the conditions to be legally bound by the License Agreement and the Ancillary Agreements upon the closing of the Transaction and to deliver to Rockefeller an updated Development Plan (as defined in the License Agreement) within forty-five (45) days after the closing date of the proposed Transaction.
- 2. Rockefeller Consent:** Rockefeller hereby consents to the assignment of the License Agreement and the Ancillary Agreements to Buyer upon the closing date of the Transaction.

If Rockefeller agrees with these terms and conditions, please have Rockefeller sign this letter agreement and forward to my attention.

Thank you for your attention to this matter.

Very truly yours,

VIRDANTE PHARMACEUTICALS, INC.

By: /s/ John W. Ripple
Name: John W. Ripple
Title: Chief Executive Office

ACKNOWLEDGED AND AGREED:

THE ROCKEFELLER UNIVERSITY

By: /s/ Kathleen A. Denis
Name: Kathleen A. Denis, Ph.D.
Title: Associate Vice President Technology Transfer

MOMENTA PHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

Accordingly, Virdante, Rockefeller and Buyer hereby agree to the terms and conditions set forth below:

1. Buyer Representations: Buyer represents to Rockefeller that it accepts the conditions to be legally bound by the License Agreement and the Ancillary Agreements upon the closing of the Transaction and to deliver to Rockefeller an updated Development Plan (as defined in the License Agreement) within forty-five (45) days after the closing date of the proposed Transaction.
2. Rockefeller Consent: Rockefeller hereby consents to the assignment of the License Agreement and the Ancillary Agreements to Buyer upon the closing date of the Transaction.

If Rockefeller agrees with these terms and conditions, please have Rockefeller sign this letter agreement and forward to my attention.

Thank you for your attention to this matter.

Very truly yours,

VIRDANTE PHARMACEUTICALS, INC.

By: _____
Name: John W. Ripple
Title: Chief Executive Office

ACKNOWLEDGED AND AGREED:

THE ROCKEFELLER UNIVERSITY

By: /s/ Kathleen A. Denis
Name: Kathleen A. Denis, Ph.D.
Title: Associate Vice President Technology Transfer

MOMENTA PHARMACEUTICALS, INC.

By: _____
Name: _____
Title: _____

EXHIBIT D

LETTER AGREEMENT WITH THE ROCKEFELLER UNIVERSITY

VIRDANTE PHARMACEUTICALS, INC.
101 Main Street, Suite 1210
Cambridge, MA 02142

November 29, 2011

Via E-mail and Federal Express

Kathleen A Denis, Ph.D.
Associate Vice President
Office of Technology Transfer
The Rockefeller University
1230 York Avenue, Box 138
New York, NY 10065

RE: Letter Agreement RE License Agreement

Dear Kathleen:

As we discussed, in connection with (i) the Second Amended and Restated License Agreement effective May 7, 2010 by and between Viridante Pharmaceuticals, Inc. ("Viridante") and The Rockefeller University ("Rockefeller") (the "License Agreement"), and (ii) the Sponsored Research Agreement dated May 7, 2007, as amended, by and between Viridante and Rockefeller (the "Sponsored Research Agreement"), Viridante and Rockefeller hereby agree as follows:

1. **Updated Rockefeller Patent Rights** . In connection with the patents and patent applications owned by Rockefeller that were added to the License Agreement under the terms of the Sponsored Research Agreement, Viridante and Rockefeller acknowledge and agree that Exhibit A to the License Agreement is hereby replaced and superseded by the Exhibit A attached to this Letter Agreement effective as of the date of this Letter Agreement.
2. **Final Payment under Sponsored Research Agreement** : In August 2011, in connection with the Sponsored Research Agreement, Viridante paid the final one-time payment of \$[**] to Rockefeller and Viridante's payment obligations under the Sponsored Research Agreement have been satisfied in full.
3. **2011 Annual License Maintenance Fees** . In August 2011, Viridante paid the annual license fee of \$[**] due on the fourth anniversary of the License

Agreement. For avoidance of doubt, Virdante's obligations under the License Agreement to pay annual license maintenance fees to Rockefeller on the fifth and six anniversaries and thereafter under Section 4.3 of the License Agreement shall remain in full force and effect.

4. **Misc.** Except as provided, herein the License Agreement shall remain in full force and effect. The License Agreement is in effect and in good standing and neither party is aware of any material breach of the License Agreement on the part of the other party as of the date of this Letter Agreement.

If Rockefeller agrees with these terms and conditions, please have Rockefeller sign this Letter Agreement and forward to my attention.

Thank you for your support of Virdante and your attention to this matter.

Very truly yours,

VIRDANTE PHARMACEUTICALS, INC.

By: /s/ John W. Ripple
Name: John W. Ripple
Title: Chief Executive Office

ACKNOWLEDGED AND AGREED:

THE ROCKEFELLER UNIVERSITY

By: /s/ Kathleen A. Denis
Name: Kathleen A. Denis, Ph.D.
Title: Associate Vice President Technology Transfer

EXHIBIT A

ROCKEFELLER PATENT RIGHTS

1. All patent rights represented by or issuing from the patents and patent applications set forth in the attached listing.

Seller's right, title, benefit, privileges and interest in and to the Assumed Liabilities and all of the Seller's burdens, obligations and liabilities in connection with each of the Assumed Liabilities and assumes and agrees to observe and perform all of the duties, obligations, terms, provisions and covenants, and to pay and discharge all of the liabilities of the Seller to be observed, performed, paid or discharged from and after the Closing in connection with the Assumed Liabilities..

Nothing contained in this Assumption Agreement shall be deemed to alter or amend the terms and provisions of the Purchase Agreement, and in the event of any conflict between the terms and provisions of this Assumption Agreement and the Purchase Agreement, the terms and provisions of the Purchase Agreement shall be deemed to govern and be controlling.

Nothing contained in this Assumption Agreement is intended to provide any right or remedy to any person or entity, other than the Seller and each third party to each Transferred Contract. Notwithstanding the foregoing, for the avoidance of doubt, with respect to matters between the Purchaser and the Seller, the terms of the Purchase Agreement shall be deemed to govern and be controlling.

This Assumption Agreement shall be construed in accordance with, and governed in all respects by, the internal laws of the Commonwealth of Massachusetts (without giving effect to principles of conflicts of laws).

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF , the parties have caused this Assumption Agreement to be executed and delivered as of the date first written above.

MOMENTA PHARMACEUTICALS, INC. ,
a Delaware corporation

By: _____
Name: Craig A. Wheeler
Title: President and Chief Executive Officer

VIRDANTE PHARMACEUTICALS, INC. ,
a Delaware corporation

By: _____
Name: John W. Ripple
Title: Chief Executive Officer

[*Signature Page to Assumption Agreement*]

EXHIBIT F

EARN-OUT

The following sets forth the various milestones (collectively, the “**Milestones**”) for the purposes of determining the Milestones Payments that may become payable pursuant to Section 1.3(b) of the Agreement. The Purchaser shall use Commercially Reasonable Efforts to achieve such Milestones.

- (a) “**Milestone #1A**” means [**];
- (b) “**Milestone #1B**” means [**];
- (c) “**Milestone #1C**” means [**];
- (d) “**Milestone #2A**” means [**];
- (e) “**Milestone #2B**” means [**];
- (f) “**Milestone #2C**” means [**];
- (g) “**Milestone #3A**” means [**];
- (h) “**Milestone #3B**” means [**]; and
- (i) “**Milestone #3C**” means [**].

If a Milestone is attained prior to the end of its applicable Milestone Measuring Period, then within thirty (30) days following the attainment of a Milestone, the Purchaser shall deliver to the Seller a certificate (the “**Milestone Compliance Certificate**”) certifying the date of the satisfaction of the applicable Milestone and that the Seller is entitled to receive the applicable Milestone Payment within fifteen (15) days after such Milestone Compliance Certificate is sent by the Purchaser (the “**Milestone Payment Date**”). If a Milestone is not attained on or before the end of the applicable Milestone Measuring Period, then on or before the date that is thirty (30) days after the end of the applicable Milestone Measuring Period, the Purchaser shall deliver to the Seller a certificate certifying the Milestone(s) that have not occurred and that the Purchaser has complied with its obligations under this Agreement.

For purposes of the section above,

- (a) “**Milestone Measuring Period**” shall mean each of the anniversary dates of the Closing Date specified above by which an applicable Milestone must be achieved.
- (b) “[**] **Product**” shall mean [**].
- (c) “**sIVIG Product**” shall mean [**].
- (d) “**Other Sialylated Product**” shall mean [**].
- (e) “[**] **Study**” means [**].
- (f) “**Valid Claim**” means (i) a claim of an issued and unexpired patent included in or related to the Patent Rights transferred pursuant to this Agreement that (A) has not been rejected, revoked or held

to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken, or (B) has not been finally abandoned, disclaimed or admitted to be invalid or unenforceable through reissue or disclaimer; or (ii) a claim included in or related to the Patent Rights transferred pursuant to this Agreement that has not been finally determined to be unallowable by the applicable governmental authority (from which no appeal is or can be taken).

For the avoidance of doubt, a [**] Product, sIVIG Product or Other Sialylated Product cannot achieve Milestone Payments in more than one Product category (*e.g.* , an Initial Product, a Second Product and an Other Sialylated Product); such Milestone categories are mutually exclusive.

EXHIBIT G

FORM OF PRESS RELEASE

Momenta Pharmaceuticals Acquires Assets From Virdante Pharmaceuticals

CAMBRIDGE, Mass., Dec. 5, 2011 (GLOBE NEWSWIRE) - Momenta Pharmaceuticals, Inc. (Nasdaq:MNTA), a biotechnology company specializing in the characterization and engineering of complex drugs, today announced that it has signed an agreement to acquire the Sialic Switch assets of Virdante Pharmaceuticals, Inc., including intellectual property and cell lines, relating to the sialylation of intravenous immunoglobulin (IVIG) and other proteins. Momenta made an upfront payment of \$4.5 million and may make additional contingent milestone payments, which, if all development and regulatory milestones are achieved, will total \$51.5 million.

“Virdante’s Sialic Switch technology represents an exciting approach to potentially regulate anti-inflammatory activity of proteins,” said Ganesh Venkataraman, Ph.D., Chief Scientific Officer of Momenta Pharmaceuticals, Inc. “Sialylation complements our existing technology platform and we look forward to advancing this technology in development programs, including biobetters and novel products.”

Virdante, a venture-backed biotechnology company, was founded in 2008 to apply its Sialic Switch technology to develop novel therapeutic treatments for autoimmune and inflammatory disorders. Virdante’s Sialic Switch technology is based on the principle of activating a novel anti-inflammatory pathway by specifically sialylating Fc-linked glycans of IgG antibodies.

About Momenta

Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex mixture drugs. Momenta is applying its technology to the development of generic versions of complex drug products, as well as to the discovery and development of novel drugs. Momenta was founded in 2001 based on technology initially developed at Massachusetts Institute of Technology and is headquartered in Cambridge, MA.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not form a part of this press release. Our logo, trademarks, and service marks are the property of Momenta Pharmaceuticals, Inc. All other trade names, trademarks, or service marks are property of their respective owners.

CONTACT: Beverly Holley
Director, Investor Relations
bholley@momentapharma.com
617-395-5189

Source: Momenta Pharmaceuticals

News Provided by Acquire Media

EXHIBIT H

FORM OF CONSENT OF [**]

VIRDANTE PHARMACEUTICALS, INC.
101 Main Street, Suite 1210
Cambridge, MA 02142

November 21, 2011

Via E-mail and Federal Express

[**]

RE: Important Confidential Matter

Dear [**]:

In connection with the Small Scale Manufacturing Agreement (the “Agreement”) by and between [**] and Virdante Pharmaceuticals, Inc. (“Virdante”) effective June 22, 2011 (the “2011 Agreement”), Virdante is writing to provide information to [**] regarding an important confidential matter. As you know, earlier this year, Virdante commenced efforts to seek a strategic acquirer or licensor (the “Strategic Process”).

In connection with the Strategic Process, I am pleased to report that Virdante is in discussions with Momenta Pharmaceuticals, Inc. or its affiliate (s) (the “Buyer”) regarding a possible transaction in which Buyer proposes to acquire all or substantially all of the assets of Virdante by means an asset purchase agreement (the “Transaction”). As you may know, Buyer is a public pharmaceutical company that develops and/or commercializes therapeutic or diagnostic products for humans and has a significant market capitalization. As a public company, Buyer’s public securities law filings are available at www.sec.gov. Buyer’s corporate address and corporate web site are as follows:

Momenta Pharmaceuticals, Inc.
675 West Kendall Street
Cambridge, MA 02142
Website: <http://www.momentapharma.com>

In connection with the Transaction, Buyer has indicated that Virdante would assign, and Buyer would assume, (i) the 2011 Agreement, (ii) Cell Line Development Services Agreement by and between Virdante and [**], dated March 31, 2010 (the “2010 Agreement”) and (iii) the Termination Agreement by and between Virdante and [**] dated June 22, 2011 (the “Termination Agreement”) and together with the 2011 Agreement and the 2010 Agreement, (the “Agreements”). Accordingly, Virdante is writing to provide notice to [**] of the proposed

assignment and seeks [**] consent in connection with the assignment of the Agreements to Buyer.

Virdante would ask [**] to formally consent in writing to the proposed assignment by Virdante, and proposed assumption, of the Agreements in connection with the Transaction. Such assignment would (i) enter into force as soon as Virdante or Momenta notifies [**] that the Transaction has taken place, and if such notification is not received by [**] by December 31, 2011, the consent from [**] as expressed through the signature below shall be void, and (ii) even after such assignment, Virdante shall, in addition to Momenta, still have towards [**] all obligations on confidentiality, non use of material and information and granting rights in inventions and in know-how, as agreed in the Agreements. If [**] agrees with these terms and conditions, please have [**] sign this Letter Agreement and forward to my attention.

Thank you for your support of Virdante and your attention to this matter.

Very truly yours,

VIRDANTE PHARMACEUTICALS, INC.

By: /s/ John W. Ripple
Name: John W. Ripple
Title: Chief Executive Officer

ACKNOWLEDGED AND AGREED:

By: [**]
Name: [**]
Title: CEO

By: [**]
Name: [**]
Title: Financial Manager

EXHIBIT I

FORM OF WAIVER AND RELEASE

December , 2011

Momenta Pharmaceuticals, Inc.
675 W. Kendall St.
Cambridge, MA 02142

Ladies and Gentlemen:

Reference is made to that certain Asset Purchase Agreement dated as of December , 2011 (the “*Asset Purchase Agreement*”), by and between Momenta Pharmaceuticals, Inc., a Delaware corporation (“*Purchaser*”) and Virdante Pharmaceuticals, Inc., a Delaware corporation (the “*Company*”), pursuant to which Purchaser will acquire substantially all of the assets of the Company (the “*Transaction*”). As has been relayed to the undersigned, the Purchaser does not intend to assume the Company’s contract with and obligations to the undersigned in connection with the Transaction.

To induce the Purchaser to execute the Asset Purchase Agreement and to consummate the Transaction contemplated thereby, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned, in his individual capacity, intending to be legally bound, hereby covenants and agrees as follows:

1. Acknowledgement. The undersigned participated in the negotiation of Transaction and is fully aware of all of the details of the Transaction.

2. Waiver. The undersigned hereby agrees not to assert against and waives any all Claims against the Purchaser that it may have, whether at law or in equity and regardless of the legal theory upon which such Claim may be based (including without limitation based upon any theory of successor liability or based upon any claim of fraudulent transfer or any other Claim alleging that the consideration paid in connection with the consummation of the Transaction is insufficient for any reason), for any failure on the part of the Company to honor any of the obligations that the Company may have (as a debtor or otherwise) to the undersigned.

3. Release. The undersigned hereby irrevocably, unconditionally and completely releases, acquits and forever discharges each of the Releasees (as defined below) from any Claim (as defined below), and hereby irrevocably, unconditionally and completely waives and relinquishes each and every Claim that the undersigned may have had in the past, may now have or may have in the future against any of the Releasees, relating to any written or oral agreements or arrangements by and between the undersigned and the Company occurring, existing or entered into at any time up to and including the date of this letter agreement.

4. For purposes of this Agreement:

(a) the term “*Releasees*” means: (i) the Purchaser; (ii) each affiliate of the Purchaser; and (iii) the successors and past, present and future assigns, directors, officers, agents,

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SCHEDULE 1.1(c)

TRANSFERRED CONTRACTS

[**]

SCHEDULE 1.1(e)

TRANSFERRED RECORDS

1. A list of the Contact Information (including email and telephone number) for the principal contacts associated with such Transferred Contracts, which list shall be delivered to the Purchaser on the Closing Date.
2. The Seller's Laboratory Notebooks, which shall be delivered to the Purchaser on the Closing Date.
3. The Seller's results of experiments that have been scanned and added to an external hard drive, which shall be delivered to the Purchaser within five (5) business days after the Closing Date.
4. The Seller's electronic documents that were included in the Seller's Virtual Data Room that were made available to the Purchaser shall be added to the Momenta External Storage Devices (as defined below), which shall be delivered to the Purchaser within five (5) business days after the later of (i) the Closing Date or (ii) the date Purchaser provides the Momenta External Storage Devices to Seller.
5. All presentations to the Seller's board of directors related to the Transferred IP, business and product plans, and market studies in the 12 months prior to the Closing Date shall be added to the Momenta External Storage Devices, which shall be delivered to the Purchaser within ten (10) business days after the later of (i) the Closing Date or (ii) the date Purchaser provides the Momenta External Storage Devices to Seller.
6. Representative examples of presentations by the Seller to investors or prospective investors related to the Transferred IP, business and product plans, and market studies in the 12 months prior to the Closing Date shall be added to the Momenta External Storage Devices, which shall be delivered to the Purchaser within ten (10) business days after the later of (i) the Closing Date or (ii) the date Purchaser provides the Momenta External Storage Devices to Seller.

For purposes of this Schedule 1.1(e) to the Agreement, the term "Momenta External Storage Devices" shall mean an external hard drive (or drives) and/or network attached storage device(s) of sufficient data storage size to hold all of the above-mentioned electronic documents referenced in this Schedule 1.1(e) to the Agreement. Purchaser acknowledges and agrees to the following:

1. Purchaser shall furnish and provide to Seller the Momenta External Storage Devices for the purpose of transferring the above-mentioned electronic documents included in the Transferred Records (and such timelines referenced above will begin on the date of such delivery);
 2. Purchaser, if requested by Seller, shall provide reasonable information technology assistance and consulting (only during normal business hours) in connection with the transfer, duplication and storage of such electronic documents (if requested by Seller, including on-site or telephonic assistance (only during normal business hours) in such process and procedures); and
 3. Purchaser shall arrange for both the delivery and pickup of such Momenta External Storage Devices once the above—mentioned electronic documents included in the Transferred Records have been transferred to such Momenta External Storage Device.
-

SCHEDULE 1.6

ALLOCATION SCHEDULE

Asset	Fair Value	
Rockefeller License Agreement	\$	[**]
IP/know-how and scientific notebooks	\$	[**]
Physical Inventory of sialylation enzyme, IVIG, [**] cell lines	\$	[**]
Fair Value of Intangible Assets	\$	[**]

Note: The contingent consideration (milestones) is not included as part of the purchase price allocation.

SCHEDULE 4.4

DISPUTE RESOLUTION

1. If any Indemnitee has incurred or suffered or claims to have incurred or suffered, or believes that it may incur or suffer, Damages for which it is or may be entitled to be held harmless, indemnified, compensated or reimbursed under Section 4 of the Agreement or for which it is or may be entitled to a monetary remedy (such as in the case of a claim based on intentional misrepresentation or fraud), such Indemnitee may deliver a notice of claim (a “**Notice of Claim**”) to the Seller or the Purchaser (each, an “**Indemnitor**”). Each Notice of Claim shall: (a) state that such Indemnitee believes that such Indemnitee is or may be entitled to indemnification, compensation or reimbursement under Section 4 of the Agreement or is or may otherwise be entitled to a monetary remedy; (b) contain a brief description of the circumstances supporting such Indemnitee’s belief that such Indemnitee is so entitled to indemnification, compensation or reimbursement or is or may otherwise be entitled to a monetary remedy; and (c) if practicable, contain a good faith, non-binding, preliminary estimate of the aggregate dollar amount of actual and potential Damages that have arisen and may arise as a result of such circumstances (the aggregate amount of such estimate, as it may be modified by such Indemnitee in good faith from time to time, being referred to as the “**Claimed Amount**”).

2. During the 30-day period commencing upon delivery by an Indemnitee to the Indemnitor of a Notice of Claim (the “**Dispute Period**”), the Indemnitor may deliver to the Indemnitee who delivered the Notice of Claim a written response (the “**Response Notice**”) in which the Indemnitor: (a) agrees that the full Claimed Amount is owed to the Indemnitee; (b) agrees that part, but not all, of the Claimed Amount (the “**Agreed Amount**”) is owed to the Indemnitee; or (c) indicates that no part of the Claimed Amount is owed to the Indemnitee. If the Response Notice is delivered in accordance with clause “(b)” or “(c)” of the preceding sentence, the Response Notice shall also contain a brief description of the facts and circumstances supporting the Indemnitor’s claim that only a portion or no part of the Claimed Amount is owed to the Indemnitee, as the case may be. Any part of the Claimed Amount that is not agreed to be owed to the Indemnitee pursuant to the Response Notice (or the entire Claimed Amount, if the Indemnitor asserts in the Response Notice that no part of the Claimed Amount is owed to the Indemnitee) being referred to as the “**Contested Amount**” (it being understood that the Contested Amount shall be modified from time to time to reflect any good faith modifications by the Indemnitee to the Claimed Amount). If a Response Notice is not received by the Indemnitee prior to the expiration of the Dispute Period, then the Indemnitor shall be conclusively deemed to have agreed that the full Claimed Amount is owed to the Indemnitee.

3. In the case where the Seller is the Indemnitor, if: (a) the Indemnitor delivers a Response Notice to the Indemnitee agreeing that the full Claimed Amount is owed to the Indemnitee; or (b) the Indemnitor does not deliver a Response Notice during the Dispute Period, then, the Claimed Amount shall be deducted from the Milestone Payments (when and if such amounts become due and payable pursuant to Section 1.3).

4. In the case where the Seller is the Indemnitor, if the Indemnitor delivers a Response Notice to the Indemnitee during the Dispute Period agreeing that less than the full Claimed Amount is owed to the Indemnitee, then, the portion of the Claimed Amount which is not the Contested Amount shall be deducted from the Milestone Payments (when and if such amounts become due and payable pursuant to Section 1.3).

5. If the Indemnitor delivers a Response Notice to the Indemnitee during the Dispute Period indicating that there is a Contested Amount, the Indemnitor and the Indemnitee shall attempt in good faith to resolve the dispute related to the Contested Amount. If the Indemnitee and the Indemnitor resolve such

dispute, then their resolution of such dispute shall be binding on the Indemnitor and such Indemnitee and a settlement agreement stipulating the amount owed to the Indemnitee (the “ **Stipulated Amount** ”) shall be signed by the Indemnitee and the Indemnitor and, in the case where the Seller is the Indemnitor, the Stipulated Amount shall be deducted from the Milestone Payments (when and if such amounts become due and payable pursuant to Section 1.3).

6. If the Indemnitor and the Indemnitee are unable to resolve the dispute relating to any Contested Amount during the 30-day period commencing upon the delivery of the Response Notice to the Indemnitee, then either the Indemnitee or the Indemnitor may submit the claim described in the Notice of Claim to the federal or state court in the County of Suffolk in the Commonwealth of Massachusetts as provided for in Section 6.6 of the Agreement. The court’s authority shall be confined to deciding: (a) whether the Indemnitee is entitled to recover the Contested Amount (or a portion thereof), and the portion of the Contested Amount the Indemnitee is entitled to recover; and (b) the non-prevailing party in the Proceeding. The final decision of the court shall include the dollar amount of the award to the Indemnitee, if any (the “ **Award Amount** ”), shall be furnished to the Indemnitor and the Indemnitee in writing and shall constitute a conclusive determination of the issue(s) in question, binding upon the Indemnitor and the Indemnitee (the “ **Resolved Amount** ”). The non-prevailing party in any such Proceeding shall pay the reasonable expenses (including reasonable attorneys’ fees) of the prevailing party, and the fees and expenses associated with the Proceeding. If an Indemnitee is found to be the prevailing party in any such Proceeding, the amount of the reasonable fees and expenses of such Indemnitee payable by the non-prevailing party pursuant to the immediately preceding sentence shall be added to the Award Amount. The non-prevailing party shall be determined solely by the court. If a Contested Amount is finally resolved, then, within 10 days after the final resolution of such Contested Amount, the Resolved Amount shall be deducted from the Milestone Payments (when and if such amounts become due and payable pursuant to Section 1.3) and the Purchaser shall pay to the Seller the sum of: the amount, if any, equal to (a) the remaining Milestone Payments (due and payable pursuant to Section 1.3); *minus* (b) the aggregate amount of the Claimed Amounts and Contested Amounts associated with all remaining Unresolved Claims.

8. In the case where the Seller is the Indemnitor, pending resolution of a Contested Amount in accordance with the foregoing procedures, the Purchaser shall be entitled to temporarily withhold the amount of such Contested Amount from any Milestone Payments. If within 180 days of the applicable Response Notice such Contested Amount has not been resolved and the Purchaser has not filed a court claim with respect to such Contested Amount in accordance with the foregoing paragraph 6 above, then such Contested Amount shall no longer be deemed a Contested Amount, and the Purchaser shall pay to the Seller such Contested Amount withheld from any Milestone Payments (when and if such amounts become due and payable pursuant to Section 1.3).

LIST OF SCHEDULES:

- Schedule 1.1(a) – Transferred IP
- Schedule 1.1(b) – Transferred Tangible Assets
- Schedule 1.1(c) – Transferred Contracts
- Schedule 1.1(e) – Transferred Records
- Schedule 1.6 – Allocation Schedule
- Schedule 4.4 – Dispute Resolution

LIST OF EXHIBITS:

- Exhibit A – Certain Definitions
 - Exhibit B – Form of Bill of Sale and Assignment Agreement
 - Exhibit C – Consent of The Rockefeller University
 - Exhibit D – Letter Agreement from The Rockefeller University
 - Exhibit E – Form of Assignment and Assumption Agreement
 - Exhibit F – Earn-Out
 - Exhibit G – Form of Press Release
 - Exhibit H – Consent of [**]
 - Exhibit I – Form of Waiver and Release
-

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EXHIBIT 21

SUBSIDIARIES OF MOMENTA PHARMACEUTICALS, INC.

<u>Name of Subsidiary</u>	<u>Jurisdiction of Organization</u>
Momenta Pharmaceuticals Securities Corporation	Massachusetts

QuickLinks

[EXHIBIT 21](#)

[QuickLinks](#) -- Click here to rapidly navigate through this document

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 333-163615, 333-161414, 333-126798, and 333-126356 and Form S-8 Nos. 333-172155, 333-164892, 333-157275, 333-149253, 333-140760 and 333-117173) of Momenta Pharmaceuticals, Inc. and where applicable, in the related Prospectuses of our reports dated February 28, 2012, with respect to the consolidated financial statements of Momenta Pharmaceuticals, Inc., and the effectiveness of internal control over financial reporting of Momenta Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2011.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 28, 2012

QuickLinks

[Exhibit 23.1](#)

CERTIFICATION

I, Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Momenta Pharmaceuticals, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 28, 2012

/s/ CRAIG A. WHEELER

Craig A. Wheeler
President and Chief Executive Officer

QuickLinks

[Exhibit 31.1](#)

CERTIFICATION

I, Richard P. Shea, Senior Vice President and Chief Financial Officer of Momenta Pharmaceuticals, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K of Momenta Pharmaceuticals, Inc.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 28, 2012

/s/ RICHARD P. SHEA

Richard P. Shea
Senior Vice President and Chief Financial Officer

QuickLinks

[Exhibit 31.2](#)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Craig A. Wheeler, President and Chief Executive Officer of the Company, and Richard P. Shea, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 28, 2012

/s/ CRAIG A. WHEELER

Craig A. Wheeler
President and Chief Executive Officer

Dated: February 28, 2012

/s/ RICHARD P. SHEA

Richard P. Shea
Senior Vice President and Chief Financial Officer

QuickLinks

[Exhibit 32.1](#)