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, 2009

or

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

For the transition period from to

Commission file number: 000-50797

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the registrant's voting shares of Common Stock held by non-affiliates of the registrant on June 30, 2009, based on $12.03 per share, the last reported sale price of Common Stock on the Nasdaq Global Market on that date, was $394,058,072.

As of February 26, 2010, the registrant had 44,838,779 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 2010 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

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PART I

Item 1. BUSINESS

The Company

Momenta is a biotechnology company specializing in the characterization and process engineering of complex molecules. These complex molecules include proteins, polypeptides, and cell surface polysaccharides, like heparan-sulfate proteoglycans, or HSPGs. This results in a diversified product pipeline of complex generic, follow-on biologic, and novel drugs. These product opportunities are derived from our proprietary, innovative technology platform which we leverage to study the *structure* (thorough characterization of chemical components), *structure-process* (understand, design and control of manufacturing process), and *structure-activity* (understand and relate structure to biological and clinical activity) of complex molecule drugs. Our development product candidates and research programs are outlined below.

Development Product Pipeline

	Product Candidate Category		
	Heparin or Heparan-Sulfate ProteoGlycan (HSPG) Based	**Complex Polypeptide**	**Therapeutic Protein**
Complex Generics	M-Enoxaparin (Generic Lovenox®)	M356 (Generic Copaxone®)	
Follow-On Biologics			Development Candidates
Novel Drug Candidates	M118 (anti-coagulant) M402 (anti-cancer)		

Our ***Complex Generics*** and ***Follow-On Biologics*** activities are focused on building a thorough understanding of the *structure-process-activity* of complex molecule drugs to develop generic versions of marketed products. While we use a similar analytical and development approach across all of our product candidates, we tailor that approach for each specific product candidate. Our first objective is to apply our core analytical technology to thoroughly characterize the *structure* of the marketed product. By defining the chemical composition of multiple batches of the marketed product, we are able to develop an equivalence window which captures the inherent variability of the innovator's manufacturing process. Using this information we then build an extensive understanding of the *structure-process* relationship to thoroughly understand, design and control our manufacturing process to reproducibly manufacture an equivalent version of the marketed product. Where necessary, and as required by the U.S. Food and Drug Administration, or FDA, we will supplement an application with additional supportive *structure-activity* data (e.g., immunogenicity, pharmacodynamics). Our goal is to obtain FDA approval for and commercialize, either directly or with collaborative partners, complex generic and follow-on biologic products thereby providing high quality, effective, safe and affordable medicines to patients in need.

Our two most advanced ***Complex Generic*** product candidates target marketed products which were originally approved by the FDA as New Drug Applications, or NDAs. Therefore, we were able to access the existing generic regulatory pathway and submitted Abbreviated New Drug Applications, or ANDAs, for these generic candidates. ***M-Enoxaparin*** is designed to be a generic version of Lovenox® (enoxaparin sodium injection), a low molecular weight heparin, or LMWH, used to prevent and treat deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. Lovenox is a complex mixture of polysaccharide chains derived from naturally sourced heparin. Our

second major generic product candidate is ***M356***, 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 complex mixture of polypeptide chains. With M356, we have extended our core characterization and process engineering capabilities from the characterization of complex polysaccharide mixtures to include the characterization of complex polypeptide mixtures. The ANDAs for both M-Enoxaparin and M356 are currently under FDA review.

In addition to our two complex generic product candidates, our ***Follow-On Biologics*** program further extends our proprietary technology platform to include the characterization and engineering of therapeutic protein products. By thoroughly characterizing these molecules, which are derived from natural or cell-based manufacturing processes, we seek to gain a deeper understanding of the relationship between the multiple steps involved in their manufacturing processes and the final product compositions. Our goal is to replicate our development approach with M-Enoxaparin and M356 and pursue the development and commercialization of biogeneric (designated by FDA to be substitutable with the marketed product) or biosimilar (designated by FDA not to be directly substitutable with the marketed drug) products.

Our ***Novel Drug*** program leverages our characterization and process engineering capabilities to develop novel drugs by studying the *structure-activity* of complex mixtures. We are targeting our efforts to understand the relationship between structure and the biological and therapeutic activity of various complex molecule drug candidates. Our goal is to capitalize on the structural diversity and multi-targeting potential of these complex molecules to engineer novel drug candidates that we believe will meet key unmet medical needs in various diseases. While we believe that our capabilities to engineer improved and novel complex molecule drug candidates can be applied across several product categories with significant therapeutic potential, our most advanced efforts have been in the area of HSPGs. Our lead novel HSPG-based drug candidate, ***M118***, has been engineered to possess what we believe will be an improved therapeutic profile compared with other currently marketed products to support the treatment of ACS. ***M402***, our second novel HSPG-based drug candidate, is in early development as a potential anti-cancer agent. We also are seeking to discover and develop additional novel HSPG-based drugs, as well as improved and novel protein drug candidates by applying our technology to better understand the function of these complex molecules in biological processes.

Company Background

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.

Our Technology

Our integrated technology platform utilizes three different types of analytical tools to study the *structure* of complex molecules. First, we have accumulated a comprehensive library of enzymes that we use to break down the components of a complex molecule into smaller, more measurable units. Second, we apply proprietary improvements to established analytical techniques (such as Matrix Assisted Laser Desorption Ionization-Mass Spectrometry, or MALDI-MS; nuclear magnetic resonance, or NMR; and capillary electrophoresis, or CE; among others) to gather and analyze information regarding the molecular components, structure and arrangement of the chemical building blocks that comprise these complex molecules. Third, we apply proprietary mathematical modeling to describe the composition of each complex molecule product candidate. It is the combination of these tools that enables us to thoroughly characterize complex HSPG, polypeptide and protein products. While a similar integrated analytical approach is applied across these different product categories, we develop a unique integrated characterization toolkit for each specific complex molecule.

Leveraging our increased resolution of the structural components of these complex molecules, we further develop analytical methods to thoroughly understand their *structure-process* relationships to design and control our manufacturing processes. In the case of our heparin and HSPG-based product candidates, for example, this includes understanding and controlling the quality of the heparin starting material as well as specific in-process parameters (depolymerization conditions, etc.) that impact final product composition. In the case of our therapeutic protein candidates, for example, this includes understanding and controlling which aspects of the manufacturing process (cell line and clonal selection, media, scale-up, etc.) contribute to the structural composition of the final product. The ability to better understand and control specific parameters in the manufacturing process which contribute to given structural signatures in the final product allows us to "reverse" engineer the process to manufacture our complex generic and follow-on biologic product candidates.

Finally, we leverage our enhanced structural and process insights to further explore the relevant *structure-activity* relationships of these complex molecules. Through this more systematic interrogation of the interplay among the various biological systems in a particular disease, we believe we can "engineer" novel HSPG and therapeutic protein drugs to address key unmet medical needs.

Product Candidates—Complex Generic and Follow-On Biologics

Overview

Our pipeline of Complex Generic and Follow-On Biologics (FOBs) product candidates leverages our technology platform across three product categories—heparins (M-Enoxaparin), polypeptides (M356), and therapeutic proteins. The goal for all of these product candidates is to utilize an abbreviated regulatory pathway to develop and commercialize generic versions of marketed products.

M-Enoxaparin—Generic Lovenox

Our most advanced complex generic product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox. An ANDA for M-Enoxaparin is currently under FDA review. Lovenox is a widely-prescribed LMWH used for the prevention and treatment of DVT and to support the treatment of ACS. Lovenox is distributed worldwide by 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.

FDA regulations and guidelines require that a generic version of a product approved under an NDA must be pharmaceutically equivalent to the branded drug product upon which the generic application is based. Generic drugs are considered pharmaceutically equivalent to their branded counterparts if, among other things, they have the same active ingredient(s), dosage form, route of administration and strength (or concentration), as well as the same labeling, with certain exceptions. For a drug to be interchangeable with the branded product, it must be therapeutically equivalent, meaning that it is pharmaceutically equivalent and bioequivalent. Bioequivalent means that the generic product candidate has the same rate and extent of absorption as the innovator product. A therapeutically equivalent product is deemed to have the same clinical effect and safety profile as the innovator product. Our ability to apply our technology to sequence and analyze complex molecules has allowed us to analyze Lovenox and develop a process to make M-Enoxaparin, a generic version of Lovenox. We believe that our generic product candidate is equivalent to Lovenox with respect to the composition of its active ingredients, its dosage form, its route of administration and its strength—properties, which are all essential to satisfying the FDA's requirements for therapeutic equivalence.

In 2003, we formed a collaboration, which we refer to as the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz Inc., affiliates of Novartis AG. 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 M-Enoxaparin in the U.S.

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 M-Enoxaparin 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.

Potential Commercial Market

Sanofi-Aventis reported worldwide sales of Lovenox of approximately $4.2 billion in 2009, with approximately $2.5 billion coming from the United States market.

Regulatory Matters

Sandoz has submitted ANDAs in its name to the FDA for M-Enoxaparin in syringe and vial forms, seeking approval to market M-Enoxaparin in the United States. The FDA is currently reviewing both of Sandoz's M-Enoxaparin ANDAs, including our manufacturing data and technology and characterization methodology. We and Sandoz are in regular communication with the FDA to address any additional questions or requests that the FDA may have as it continues the review of Sandoz's applications. The FDA has not requested human clinical trials at this time. However, there can be no assurances that the FDA will not require additional studies, including clinical studies, in the future and we cannot predict with a high degree of certainty the timing of any potential approval of the M-Enoxaparin ANDAs by the FDA. We and Sandoz are also in active dialogue with the FDA regarding the sourcing and processing of our heparin supply. We and Sandoz are working together to prepare for the commercialization of M-Enoxaparin, if and when approved, by advancing manufacturing, supply chain, and sales and marketing objectives.

Both ANDAs included a Paragraph IV challenge to the Sanofi-Aventis Orange Book patents for Lovenox. The Orange Book patents were found to be unenforceable due to inequitable conduct in a 2008 decision of the Court of Appeals of the Federal Circuit in the case of Aventis v. Amphastar Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. Consequently, Sanofi-Aventis' patent infringement case against Sandoz for infringement of the Orange Book patents was finally dismissed on August 27, 2009, removing any Orange Book patent barrier to approval.

Sanofi-Aventis US LLC has filed a citizen petition with the FDA regarding the approval of any ANDAs filed for generic Lovenox. Until such time as the FDA completes its review of the ANDAs and rules on the citizen petition, Sandoz and Momenta remain subject to further questions and inquiry by the FDA. Following an FDA decision on the citizen petition, Sanofi-Aventis may seek judicial review and request judicial relief that might include emergency, temporary and permanent injunctive relief, which if granted could interfere with a product launch of M-Enoxaparin.

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. Multiple sclerosis is 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 ingredients as Copaxone.

Potential Commercial Market

In North America, Copaxone is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. In Europe, Copaxone is marketed by Teva Pharmaceutical

Industries Ltd. and Sanofi-Aventis. Teva reported worldwide sales of Copaxone of approximately $2.8 billion in 2009, with approximately $1.9 billion from the U.S.

Regulatory Matters

In December 2007, our collaborative partner, Sandoz, submitted to the FDA an ANDA in its name containing a Paragraph IV certification seeking approval to market M356 in the United States. 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. The FDA's 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.

Legal Matters

Teva has listed seven patents in the Orange Book for Copaxone, all of which expire in May 2014. All of the Orange Book patents belong to the same patent family and have virtually identical disclosures and priority dates. Two additional patents belonging to the same patent family are not listed in the Orange Book. In August 2008, in response to Sandoz's ANDA filing and the Paragraph IV certification, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and us for patent infringement of some, but not all, of the Orange Book Patents. The initiation of this litigation triggered an automatic 30-month stay of ANDA approval. In our answer to this lawsuit, we, Sandoz and Novartis AG asserted defenses of non-infringement, invalidity, and unenforceability of the patents and filed counterclaims for declaratory judgments to have all nine of the patents in the same patent family adjudicated in the present lawsuit. This litigation is ongoing. The ability to commercialize and launch M356 depends, in part, upon the final outcome of this litigation. While we and Sandoz believe we will prevail and will vigorously defend the case, we cannot be certain when the outcome of the litigation will be final and whether we and Sandoz will ultimately prevail.

Follow-On Biologics (FOBs) Program

We are also applying our technology platform to the development of FOBs, including either generic or 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 2010. 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 glycoprotein drug and can often comprise a significant portion of the mass of the molecule.

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. Presently, there is no abbreviated regulatory pathway for the approval of generic or biosimilar versions of BLA-approved products in the United States; however, there are emerging guidelines for biosimilar products in the European Union. We believe that scientific progress in the analysis and characterization of complex mixture drugs is likely to play a significant role in the creation of an appropriate abbreviated U.S. regulatory pathway in the future.

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.

Product Candidates—Novel Drugs

Overview

Our novel drug research and development program currently builds off the established characterization and process engineering capabilities from our complex generic and FOB programs—with a focus on cell surface polysaccharides, like HSPGs, and therapeutic proteins. We believe our 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. With HSPGs, our goal is to leverage the multi-targeting nature of these molecules to develop novel HSPG-based therapeutics where we can positively affect multiple pathways in a disease with a single drug. We are currently focused on anticoagulation and cancer; however, because of the broad role of HSPGs in biology, we plan to target multiple disease areas with this therapeutic approach. While not yet as advanced as our HSPG program, we also are extending these biological systems insights into the development of improved and more targeted protein therapeutics.

M118

Our most advanced novel drug HSPG-based product candidate, M118, is being developed as an anticoagulant for ACS. M118 is a LMWH which has been rationally designed to capture, in a single therapy, the positive attributes of both unfractionated heparin (reversibility, monitorability and broad inhibition of the coagulation cascade) and LMWH (adequate bioavailability and predictable pharmacokinetics to allow for convenient subcutaneous administration). We believe that M118 has the potential to provide improved baseline anticoagulant therapy for the medical management of patients diagnosed with ACS who may or may not require coronary intervention in order to treat their condition.

Description of Our Program

ACS includes several diseases ranging from unstable angina, which is characterized by chest pain at rest, to acute myocardial infarction, or heart attack, which is caused by a complete blockage of a coronary artery. Currently, a majority of patients are initially medically managed with an anti-clotting agent, such as LMWH or unfractionated heparin, or UFH, in combination with other therapies. An increasing proportion of ACS patients are also proceeding to early intervention with procedures such as angioplasty or coronary artery bypass grafting, or CABG. Both angioplasty and CABG require anticoagulant therapy to prevent clot formation during and immediately following the procedure.

M118 was rationally designed utilizing our proprietary technology platform to address multiple desirable clinical attributes of anticoagulation therapy for ACS in a single agent. These engineered attributes of M118 include, among others, broad inhibition of the coagulation cascade, monitorability, reversibility, and predictable pharmacokinetics. M118 may also be administered both intravenously and subcutaneously, allowing physicians the ability to institute convenient subcutaneous therapy during the medical management phase of ACS treatment and continue the same anticoagulant administered intravenously should an interventional procedure be required. We believe that the properties of M118 observed to date in both preclinical and clinical investigations support our design hypothesis that M118 can be effectively used in multiple settings (including medical management, angioplasty or CABG) and that M118 may provide physicians with an effective, safe, and more flexible treatment option than is

currently available. The results of our preclinical and clinical studies conducted to date suggest potential benefits of M118 over UFH and other LMWHs, including:

- *Increased efficacy.* In animal studies directly comparing M118 with UFH and other LMWHs, M118 appeared to more effectively prevent clotting of injured arteries in a rat, rabbit and canine thrombosis model. The results of *in vivo* and *in vitro* experiments suggest that M118 acts at multiple points in the coagulation cascade by inhibiting Factor Xa, Factor IIa, Factor IXa and through the release of tissue factor pathway inhibitor. Purported advantages of M118 in humans will need to be confirmed in future trials.
- *Reversibility.* Animal and human studies also demonstrate that the anti-clotting effects of M118 are reversible by administering protamine sulfate, the standard drug used to reverse anticoagulant activity. Existing marketed LMWHs are not fully reversible with protamine.
- *Ability to monitor.* Due to the presence of certain saccharide sequences in M118, the anti-clotting activity of M118 can be monitored by standard, point-of-care laboratory tests that detect the presence of Factor IIa, or thrombin, such as activated clotting time, or ACT, (routinely used during interventional procedures), and activated partial thromboplastin time. Currently, existing marketed LMWHs cannot be monitored efficiently with such routine laboratory tests.

We believe that the results of clinical trials conducted to date support continuing the evaluation of M118 in patients diagnosed with ACS who are medically managed with or without an intervention.

Potential Commercial Market

The broad anticoagulant market is projected to generate greater than $10.0 billion in worldwide sales by 2018. Depending upon the indications for which M118 use is approved, M118 has the potential to capture a portion of this market.

Regulatory and Clinical Development

In July 2006, we submitted an Investigational New Drug Application, or IND, with the FDA for our M118 intravenous injection product and in October 2006 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. In June, 2009, we completed a Phase 2a clinical trial to evaluate the feasibility of utilizing M118 intravenous injection as an anticoagulant in patients with stable coronary artery disease undergoing percutaneous coronary intervention. This trial, known as EMINENCE (Evaluation of M118 in Percutaneous Coronary Intervention), enrolled approximately 500 patients with stable coronary artery disease undergoing elective Percutaneous Coronary Intervention. Patients were randomly assigned to receive treatment with one of three doses of intravenous M118 or a standard dose of UFH. The primary endpoint of the study was the combined incidence of clinical events defined as the composite of death, myocardial infarction, repeat revascularization, and stroke (over thirty days); incidence of bleeding and thrombocytopenia (over the first 24 hours); and bailout use of glycoprotein IIb/IIIa inhibitors and catheter thrombus (during the procedure). The primary analysis in the study provided evidence of non-inferiority of the combined M118 group (combining all three doses) as compared to the UFH group within the parameters of the prospectively defined analysis. The observed incidence of the primary endpoint was lower in all M118 treatment groups than in the UFH group; however it should be noted that the study was not designed or powered to detect statistically significant differences between treatments. The incidence of serious and non-serious adverse events was comparable in all treatment groups.

In March 2007, we submitted an IND for our M118 subcutaneous injection product and in May 2007 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. These trials have been completed.

We are not currently able to estimate the timing or probability of regulatory approval of M118. We are seeking a collaborative partner to finance and support the further clinical development of M118. We will not start additional clinical trials until we have a partner or funding available, but we do remain committed to the product candidate and its continued development.

M402

M402 is our next most advanced novel HSPG-based product candidate and is engineered to have potent anti-cancer properties and low anticoagulant activity. HSPGs are complex molecules present in the tumor microenvironment which play a role in the conversion of normal cells into cancerous cells and present growth factors, cytokines, and chemokines necessary for tumor cell growth, migration, and survival. M402 is designed to exploit this biology. Data from preclinical studies have shown that M402 has the potential to modulate angiogenesis and tumor metastasis through a variety of HSPG-binding proteins. We currently have plans to advance M402 into human clinical trials in the first half of 2011.

Research and Development Expenses

Research and development expenses consist of costs incurred in identifying, developing and testing our product candidates. 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 2009 was $60.6 million, compared with $55.3 million in 2008 and $69.9 million in 2007.

Collaborations and Licenses

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.

Under this collaboration, Sandoz makes certain payments to us. As mutually agreed, we provide, and Sandoz pays us, for internal expenses incurred in scientific, technical and/or management work. Sandoz is also responsible for funding substantially all of the other ongoing development and commercialization costs and legal expenses incurred with respect to injectable enoxaparin, subject to termination rights upon reaching agreed upon limits. In addition, Sandoz will, in the event there are no third party competitors marketing a Lovenox-Equivalent Product, as defined in the collaboration agreement, provide to us a share of the profits from M-Enoxaparin. This profit share percentage is between 40%–50%. If another interchangeable generic Lovenox is on the market, we are entitled to receive a royalty on net sales by Sandoz. That royalty rate ranges from high single to low double digits. If the only competitor to M-Enoxaparin is an authorized generic, we receive hybrid economics—a royalty up to a specified sales level, then a profit share on net sales above the sales cut-off. In addition, if certain milestones are achieved with respect to injectable enoxaparin under certain circumstances, Sandoz may also make milestone payments to us which would reach $55.0 million if all such milestones are achieved. In all of these scenarios, a portion of the development expenses and certain legal expenses which have exceeded a specified amount will be offset against the profit-sharing amounts, royalties and milestone payments. Sandoz may also offset a portion of any product liability costs and certain other expenses arising from patent litigation against the profit-sharing amounts, royalties and milestone payments.

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 sole authority to make decisions with respect to any litigation claiming that the manufacture, use or sale of the injectable enoxaparin product infringes any patents listed in the Orange Book for Lovenox.

In addition, Sandoz has the sole authority to determine whether or not to launch M-Enoxaparin prior to receipt of final legal clearance from any such infringement claims, as well as determine the price at which it will sell M-Enoxaparin.

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 Sanofi-Aventis, claiming that the manufacture, use or sale of injectable enoxaparin infringes any patents listed in the Orange Book for Lovenox, any product liability claims with respect to injectable enoxaparin and any other claims relating to the development and commercialization of injectable enoxaparin. 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 injectable enoxaparin 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 negotiation with respect to certain of our other products and 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 M-Enoxaparin 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 M-Enoxaparin 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 U.S. For M356 outside of the U.S. and for

M-Enoxaparin 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 candidates remaining under collaboration. None of these payments, once received, are 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.

Massachusetts Institute of Technology

In December 2001, we entered into a patent license agreement with the Massachusetts Institute of Technology, or M.I.T., pertaining to the characterization and synthesis of polysaccharides for the purpose of researching, developing and commercializing products (other than sequencing machines) and processes under the licensed patents. This agreement was subsequently amended and restated in early November 2002 and has been subsequently further amended. We entered into an additional

patent license agreement with M.I.T. in late October 2002 which gave us the right to develop and commercialize sequencing machines. Subject to typical retained rights of M.I.T. and the U.S. government, these two agreements grant 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 $82,500 to $132,500. 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 $132,500, $107,500 and $82,500 as expenses related to these agreements in the years ended December 31, 2009, 2008 and 2007, respectively.

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 60 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 M118 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.

Asset Purchase

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 (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.

Manufacturing

We do not own facilities for manufacturing any products. Although we intend to rely on contract manufacturers, we have personnel with experience in manufacturing, as well as process development, analytical development, quality assurance and quality control. Under the 2003 Sandoz Collaboration and the 2006 Sandoz Collaboration, Sandoz is responsible for commercialization, including manufacturing, of the products covered by those agreements.

We have entered into various agreements with third party contractors for process development, analytical services and manufacturing. In each of our agreements with contractors, we retain ownership of our intellectual property and generally own and/or are assigned ownership of processes, developments, data, results and other intellectual property generated during the course of the performance of each agreement that primarily relate to our products. Where applicable, we are granted non-exclusive licenses to certain contractor intellectual property for purposes of exploiting the products that are the subject of the agreement and in a few instances we grant non-exclusive licenses to the contract manufacturers for use outside of our product area. The agreements also typically contain provisions for both parties to terminate for material breach, bankruptcy and insolvency.

The starting material for manufacture of M402, M118 and M-Enoxaparin is UFH. In 2008, due to the occurrence of adverse events associated with the use of contaminated UFH, there were global recalls, including in the United States, of UFH products. Based on its investigation, the FDA identified a heparin-like contaminant in the implicated UFH products and recommended that manufacturers and suppliers of UFH use additional tests to screen their UFH active pharmaceutical ingredient. As a result of these UFH product recalls and potential future recalls, the U.S. government has placed certain

restrictions, and may decide to place additional restrictions, on the import of raw materials, 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 or 2006 Sandoz Collaboration, 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.

Competition

The development and commercialization of pharmaceutical products is highly competitive. Many of our competitors are working to develop or already market products similar to those we are developing and have considerable experience in product development and in obtaining regulatory approval to market pharmaceutical products. 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.

In the event that we receive approval for, market and sell M-Enoxaparin, we would face competition from Sanofi-Aventis, the company currently marketing Lovenox, and from other firms if they receive marketing approval for generic versions of Lovenox. Sanofi-Aventis may also choose to market a generic version of Lovenox itself or through an authorized third-party distributor. While there are no generic versions of Lovenox approved by the FDA to date, ANDAs have been submitted to the FDA by Amphastar, Teva and 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 our M-Enoxaparin product, should it be approved by the FDA. 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 injectible and oral anticoagulant drugs in development for the treatment of DVT, including next-generation LMWHs and several Factor Xa or Factor IIa inhibitors that are in clinical trials. The Factor Xa inhibitors include rivaroxaban, which is being developed by Bayer AG and Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and apixaban, which is being developed by Bristol-Myers Squibb Company. The Factor IIa inhibitors in development include dabigatran etexilate, which is being developed by Boehringer Ingelheim GmbH.

In the event that we receive approval for, market and sell M356, we would face competition from a number of sources. We would face competition from Copaxone, which is marketed by Teva Neuroscience, Inc. in the U.S. and 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 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 divison 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., and Betaseron (interferon-beta-1b), which is marketed by Bayer HealthCare Pharmaceuticals Inc., the U.S. pharmaceuticals affiliate of Bayer Schering Pharma AG, in the U.S. and is marketed under the name Betaferon by Bayer Schering Pharma, a division of Bayer AG, in the European Union.

In addition to the marketed products, a number of companies are working to develop products to treat multiple sclerosis. For example, an oral formulation of cladribine (developed by Merck Serono) was filed with the European Medicines Agency, or EMA, and is the subject of discussions with the FDA regarding a re-filing for approval as a therapy for Multiple Sclerosis. In addition, FTY720 (fingolimod), developed by Novartis AG, has been filed with the EMA and FDA for approval as an oral therapy for Multiple Sclerosis and BG-12, developed by Biogen Idec Inc., an oral compound that is being tested in relapsing multiple sclerosis, has been granted fast track status by the FDA.

Our M118 product is targeted to support treatment of patients with ACS. Potential competitive products to M118 include the Medicines Company's direct thrombin inhibitor, Angiomax®, which is approved for use in angioplasty, and various other LMWH and unfractionated heparin products, including Lovenox. In addition, GlaxoSmithKline's Arixtra, which is indicated for the prophylaxis of DVT and prophylaxis and treatment of DVT and pulmonary embolism, has a pending application to treat patients with ACS, though it is not currently approved in this indication. Several other anticoagulant drugs are in development for ACS, included synthetic Factor Xa and Factor IIa inhibitors and aptamer-based therapies. M118 also faces competition from products other than anticogulants, such as oral and injectible platelet inhibitors, which may be used in the treatment of ACS.

In the field of complex molecules, there are a number of potential competitors seeking to provide additional characterization or create biosimilar, generic, and/or improved versions of marketed complex products. There has been substantial growth in recent years in the number of generic and pharmaceutical companies looking to develop biosimilar or generic 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 glycobiology 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 and Biogen Idec Inc. have successfully improved products through sugar modification. Potential competitors with broad glycobiology capabilities include Optimer Pharmaceuticals, Inc., Keryx Pharmaceuticals and Pro-Pharmaceuticals, Inc. as well as many private, start-up pharmaceutical organizations. Many of these companies are focused on providing services to pharmaceutical companies rather than focused on drug discovery and product development.

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 varies depending on whether the drug is a new product whose safety and effectiveness has not previously been demonstrated in humans, or a drug whose active ingredient(s) and certain other properties are the same as those of a previously approved drug. Approval of new drugs and biologics follows the NDA and BLA routes, respectively, and a drug that claims to be the same as an already approved NDA drug may be able to follow the ANDA route. Presently, there is no statutory route for an abbreviated approval of a therapeutic protein product that has been originally approved under 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 for products 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 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 still evolving. Additionally, for therapeutic protein drugs approved by the BLA regulatory pathway, no abbreviated regulatory pathway currently exists. Although, to our knowledge, the FDA has not provided official guidance on the legal and scientific aspects of follow-on biologics regulation, legislation has been proposed each year since 2006 to establish an abbreviated approval pathway, including legislation proposed as part of the health care

reform initiatives currently underway. We anticipate this pending legislation will be the subject of significant Congressional debate in the near future, as well as lobbying efforts by both generic and branded pharmaceutical companies.

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. The FDA, however, does not always waive requirements for *in vivo* bioequivalence data. For example, bioequivalence data was required for the M-Enoxaparin ANDA submission.

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. This particular circumstance does not apply to M-Enoxaparin but may apply to future generic products that we pursue. 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.

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 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.

NDA and BLA Approval Processes

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.

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 or BLA, 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, or ANDA 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.

Follow-On Biologics

The BLA regulatory pathway was created to review and approve new applications for drugs that are typically produced from living systems. Presently, there is no abbreviated regulatory pathway for the approval of generic or biosimilar versions of BLA-approved products in the United States; however, there are emerging biosimilar guidelines in the European Union. Proposed legislation would, if enacted, create a regulatory pathway at the FDA for applicants to seek approval of follow-on biologics. We believe that scientific progress in the analysis and characterization of complex mixture drugs may influence the content of such a U.S. regulatory pathway in the future. Depending on whether such legislation is enacted, and the content of the legislation, the FDA could ultimately have the authority to exercise its discretion to approve follow-on biologics with limited clinical testing or without the need for clinical trials, and follow-on biologic manufacturers could seek to challenge the patent rights of branded products prior to commercial launch. We are not able to predict whether future legislation in this area will follow the existing ANDA process or an alternative approach and our ability to pursue our follow-on biologic opportunities is dependent on the enactment of legislation as well as the content of any resulting legislation.

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.

Employees

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of December 31, 2009, we had 176 employees, including a total of 52 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 Geographic Areas

See the section entitled "Segment Reporting" appearing in Note 2 to our consolidated financial statements 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.

Item 1A. RISK FACTORS

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. 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. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

Risks Relating to our Business

We have a limited operating history and have incurred a cumulative loss since inception. If we do not generate significant revenues, we will not be profitable.

We have incurred significant losses since our inception in May 2001. At December 31, 2009, our accumulated deficit was $321.0 million. We have not generated revenues from the sale of any products to date. We expect that our annual operating losses will increase over the next several years as we expand our drug commercialization, development and discovery efforts. To become profitable, we must successfully develop and obtain regulatory approval for our existing drug candidates, and effectively manufacture, market and sell any drugs we successfully develop. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve profitability.

To become and remain profitable, we must succeed in developing and commercializing drugs with significant market potential. This will require us to be successful in a range of challenging activities: developing drugs; obtaining regulatory approval for them through either existing or new regulatory approval pathways; clearing allegedly infringing patent rights; and manufacturing, distributing, marketing and selling them. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and 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.

If we fail to obtain approval for and commercialize our most advanced product candidate, M-Enoxaparin, we may have to curtail our product development programs and our business would be materially harmed.

We have invested a significant portion of our time, financial resources and collaboration efforts in the development of our most advanced product candidate, M-Enoxaparin, a technology-enabled generic

version of Lovenox. Our near-term ability to generate revenues and our future success, in large part, depend on the successful development and commercialization of M-Enoxaparin.

In accordance with our 2003 Sandoz Collaboration, Sandoz has submitted ANDAs to the FDA seeking approval to market M-Enoxaparin in the United States. The ANDA review process by FDA is ongoing. If any of the following occurs, we may never realize revenue from this product, we may have to curtail our other product development programs and, as a result, our business would be materially harmed:

- if we fail to answer any question from the FDA to its satisfaction as it proceeds with its review of the M-Enoxaparin ANDA, including questions relating to the potential immunogenicity of the drug product;
- if we are unable to satisfactorily demonstrate therapeutic equivalence of M-Enoxaparin to Lovenox;
- if the FDA disagrees with our characterization approach or does not agree that M-Enoxaparin is equivalent to Lovenox;
- if we otherwise fail to meet FDA requirements for obtaining ANDA approval (including, but not limited to, manufacturing and bioequivalence requirements); or
- if we fail to obtain FDA approval for, and successfully commercialize, M-Enoxaparin.

If other generic versions of Lovenox are approved and successfully commercialized, our business would suffer.

In March 2003, Amphastar and Teva each submitted ANDAs for generic versions of Lovenox with the FDA. In 2007, Hospira, Inc. submitted ANDAs for generic versions of Lovenox with the FDA. In addition, other third parties, including, without limitation, Sanofi-Aventis, may seek approval to market generic versions of Lovenox in the United States. If a competitor obtains FDA approval or if Sanofi-Aventis decides to market its drug as a generic or license it to another company to be sold as a generic, both known as authorized generics, the financial returns to us from the sale of M-Enoxaparin would be significantly less than if no other generics are approved. Under these circumstances, we may not gain any competitive advantage and the resulting market price for our M-Enoxaparin product may be lower, our commercial launch may be delayed or we may not be able to launch our product at all. Also, we may never achieve significant market share for M-Enoxaparin if one or more third parties markets generic versions of Lovenox.

The 2003 Sandoz Collaboration contains terms which specify the sharing of commercial returns of M-Enoxaparin between us and Sandoz. Under circumstances when one or more third parties successfully commercialize a generic version of Lovenox, significantly less favorable economic terms for us would be triggered. Consequently, if other generic versions of Lovenox are approved and commercialized, our revenues from M-Enoxaparin would be reduced and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, would suffer.

If efforts by manufacturers of branded products to delay or limit the use of generics are successful, our sales of technology-enabled generic products may suffer.

Many manufacturers of branded products have increasingly used legislative, regulatory and other means to delay competition from manufacturers of generic drugs. 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 Citizens Petitions in U.S. Federal District Court 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.

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 until and unless the FDA determines that the manufacturing process used by the generic applicant is equivalent to the process used to make Lovenox, or until the generic applicant demonstrates through clinical trials that its product is equally safe and effective as Lovenox, and unless the generic product is shown to contain a specific molecular structure. Teva, Amphastar, and others have filed comments opposing the Sanofi-Aventis Citizen Petition, and Sanofi-Aventis has filed numerous supplements and reply comments in support of its Citizen Petition. The FDA has yet to rule on the Sanofi-Aventis Citizen Petition, and if the FDA ultimately grants the Sanofi-Aventis Citizen Petition, or if Sanofi-Aventis successfully appeals the denial of the Citizen Petition, we and Sandoz may be unable to obtain approval of our ANDA for M-Enoxaparin, which would materially harm our business.

In November 2009, Teva Neuroscience, Inc. (on behalf of Teva Pharmaceutical Industries Ltd.) filed a Citizen Petition with the FDA requesting that the FDA neither approve nor accept for filing any ANDA for a generic version of Copaxone because the complexity of Copaxone makes it impossible to demonstrate that the active ingredient in the generic version is the same as Copaxone. If the FDA ultimately grants the Citizen Petition, we and Sandoz may be 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 Pharmaceutical Industries Ltd., 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 July 2008, the FDA accepted for review the ANDA containing a paragraph IV certification for generic Copaxone submitted by Sandoz. Subsequently, in August 2008, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and us for patent infringement related to four of the seven Orange Book patents listed for Copaxone. We, Sandoz, and Novartis AG have 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. In December 2009, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and us for patent infringement related to certain non-Orange Book patents. 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 Novartis AG, Sandoz or we will prevail in any lawsuit with Teva Pharmaceutical Industries. In addition, Teva Pharmaceutical Industries has significant resources and any litigation with Teva Pharmaceutical Industries 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 Inc. 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 M-Enoxaparin or 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 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 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. 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. 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 of the product or to meet future demand, 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 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 product candidates, including M-Enoxaparin. 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 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 pre-approval manufacturing requirements for our product candidates, or to maintain compliance with applicable regulatory standards, or are unable to produce our products in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, our revenues and gross margins could be adversely affected.

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, 2009, we had cash, cash equivalents and marketable securities totaling $95.7 million. For the year ended December 31, 2009, we had a net loss of $64.0 million and used cash in operating activities of $55.3 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, preclinical testing and clinical trials of our drug candidates, as well as funds necessary to manufacture and market any 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 advancement of our generic product candidates and other development programs, including the timing of regulatory approvals;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation, including with Teva Pharmaceuticals Industries relating to Copaxone, 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 time and costs involved in obtaining regulatory approvals;
- 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 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 your 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 revenues, 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 is primarily a hospital-based product, we expect to derive a large percentage of our future revenue for M-Enoxaparin 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 hope to establish contracts may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours, limiting access of M-Enoxaparin 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, future sales of our products, including M-Enoxaparin and M356, our revenues 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 these product candidates by patients, physicians and third-party payors. Acceptance of our product candidates 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 revenues from product sales to maintain or grow our business.

We utilize new technologies in the development of some of our products that have not been reviewed or accepted by regulatory authorities.

The approvals of some of our products in current or future development, including M-Enoxaparin and M356, are based upon new technologies that may have not previously been accepted by the FDA or other regulatory authorities. The FDA's review and acceptance of our technologies may take time and resources, or require independent third-party analysis. Alternatively, our technologies may not be accepted by the FDA and other regulatory authorities. For some of our products, the regulatory approval path and requirements may not be clear, which could add significant delay and expense. Delays or failure to obtain regulatory approval of any of the products that we develop would adversely affect 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 drug products, we may have difficulty managing our growth and expanding our operations successfully.

As we advance our drug 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, several jurisdictions such as the District of Columbia and the Commonwealth of Massachusetts have imposed licensing requirements for sales representatives and 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. 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.

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 candidates, including M-Enoxaparin and M356, as therapeutic equivalents to their corresponding reference listed drugs, 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 generic versions of complex drugs, such as M-Enoxaparin and M356. We will be required to demonstrate to the satisfaction of the FDA, among other things, that our generic products:

- contain the same active ingredients as the branded products upon which they are based;

- are of the same dosage form, strength and route of administration as the branded products upon which they are based, and have the same labeling as the approved labeling for the branded products, with certain exceptions; and
- meet 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 our generic versions of complex drugs to the reference listed drugs 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 our products or that our products and their respective branded drugs 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 any of our generic product candidates will receive FDA approval as therapeutically equivalent to its reference branded product.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of Lovenox, Copaxone or other complex drug products, does not establish standards for interchangeability for generic versions of complex drug products, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of some of our development candidates could be delayed or prevented or become more expensive. Delays in any part of the process or our inability to obtain regulatory approval for our products could adversely affect our operating results by restricting or significantly delaying our introduction of new products.

Even if we are able to obtain regulatory approval for our generic product candidates, including M-Enoxaparin and M356, as therapeutically equivalent, state pharmacy boards or agencies may still conclude that our products are not substitutable at the pharmacy level for the referenced listed drug. If our generic product candidates are not substitutable at the pharmacy level for their referenced listed drugs, this could materially reduce sales of our product candidates 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.

If the United States Congress does not take action to create an abbreviated regulatory pathway for follow-on biologics, or if the FDA is not able to establish specific guidelines regarding the scientific analyses required for characterizing follow-on biologics product candidates, then the uncertainty about the potential value of our glycoprotein program will be increased.

The regulatory climate in the United States for follow-on versions of biologics and complex protein products remains uncertain. Although there has been legislative activity over the last several years,

there is currently no established statutory or regulatory pathway for approval of follow-on versions of biologics and most protein drugs. The FDA has approved the majority of new protein products under the Public Health Service Act, or PHSA, through the use of Biologic License Applications, or BLAs. There is no provision in the PHSA for an abbreviated BLA approval pathway comparable to an ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, and the FDA has stated it does not believe it has the authority to rely on prior BLA approvals or on their underlying data to approve follow-on products. Moreover, even for proteins originally approved as NDAs under Section 505(b) of the FDCA, there is uncertainty as to what data the FDA may require to demonstrate the sameness required for approval of an ANDA. In addition, there has been opposition to the FDA's use of section 505(b)(2), which allows an applicant to rely on information from published scientific literature and/or a prior approval of a similar drug, to approve follow-on versions of protein and other complex drug products approved under section 505(b)(1) of the FDCA.

Although the FDA has previously stated its intention to draft guidance that is broadly applicable to follow-on protein products, the agency has not issued such guidance to date and may never do so. Protracted timelines and failure of the FDA to establish standards for approval of follow-on protein products or failure of the United States Congress to enact legislation establishing an abbreviated pathway for approval of follow-on biologics could reduce the value of, or render obsolete, our glycoprotein program. Moreover, even if the United States Congress enacts legislation establishing a pathway for approval of follow-on biologics, the nature of the pathway, the timing of the implementation, and the procedures enacted for utilizing the pathway could also reduce the value, or render non-competitive, our therapeutic protein program.

If our preclinical studies and clinical trials for our development candidates, including M118 and 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 M118, 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 to conduct additional clinical trials or other testing of M118, M402 or our future product candidates, 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 drug 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 revenues and profits will not develop or increase.

Our revenues 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 revenues, 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, Congress is currently considering legislation that would dramatically overhaul the U.S. health care system, including the possibility of creating a government health care plan. As part of this legislative initiative, Congress is considering a number of proposals that are intended to reduce or limit the growth of health care costs, which could significantly change the market for pharmaceuticals and biological products. While we cannot predict whether any legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and potential profitability.

In addition, Congress has from time to time considered other legislation, which if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States and which may include re-importation from foreign countries where drugs are frequently sold at lower prices than in the United States; other proposed legislation would have removed restrictions on CMS' ability to negotiate discounts directly with prescription drug manufacturers provided through the Medicare program. Such legislation, or similar regulatory changes, could decrease the reimbursement we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition.

Foreign governments tend to impose strict price or reimbursement controls, which may adversely affect our revenues, if any.

In some foreign countries, particularly the countries of the European Union, the pricing and/or reimbursement of prescription pharmaceuticals is 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, 2009, 2008 and 2007, we spent approximately $125,000, $65,000 and $64,000, respectively, in order to comply with environmental and waste disposal regulations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. 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. Although we maintain workers' compensation insurance as prescribed by the Commonwealth of Massachusetts and, for claims not covered by workers' compensation insurance, employer's liability insurance, to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. 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.

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.

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 revenues 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. The costs and uncertainties 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 injectable enoxaparin, 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 injectable enoxaparin 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 M-Enoxaparin, 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 injectable enoxaparin 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 completing the development and commercialization of injectable enoxaparin. If Sandoz terminates the 2003 Sandoz Collaboration due to our uncured breach or bankruptcy, Sandoz would retain the exclusive right to develop and commercialize injectable enoxaparin in the United States. In that event, we would no longer have any influence over the development or commercialization strategy of injectable M-Enoxaparin 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, our introduction of M-Enoxaparin may be significantly delayed, we may decide to discontinue the M-Enoxaparin project, or our revenues 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 in April 2008, 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 revenues may be significantly reduced either of which could have a material adverse effect on our business.

We may need or elect to enter into alliances or collaborations with other companies to fund our development efforts or to supplement and enhance our own capabilities. If we are unsuccessful in forming or maintaining these alliances on favorable terms, or if any collaborative partner terminates or fails to perform its obligations, our business could be adversely affected.

Because we have limited or no capabilities for manufacturing, sales, marketing and distribution, and because we have limited resources, we may need to enter into alliances or collaborations with other companies that can assist with the development and commercialization of our product candidates, such as M118. In those situations, we would expect our alliance or collaborative partners to provide substantial capabilities in manufacturing, sales, marketing and distribution. We may not be successful in entering into any such alliances. Even if we do succeed in securing such alliances, we may not be able to maintain them.

Factors that may affect the success of our collaborations include the following:

- disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;
- our collaborators may pursue alternative technologies or develop alternative products, either on their own or in collaboration with others, that may be competitive with the products on which they are collaborating with us or which could affect our collaborators' commitment to our collaborations;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the business and financial communities;
- our collaborators may pursue higher-priority programs or change the focus of their development programs, which could affect the collaborators' commitment to us; and
- our collaborators with marketing rights may choose to devote fewer resources to the marketing of our product candidates, if any are approved for marketing, than to products from their own development programs.

In addition to relying on a third party for its capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our drug candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop particular drug candidates internally, or to bring drug candidates to market. Failure or delays in bringing our drug candidates to market will reduce their competitiveness and prevent us from generating sales revenues, which may substantially harm our business.

Furthermore, in an effort to continually update and enhance our proprietary technology platform, we enter into agreements with other companies to develop, license, acquire and/or collaborate on various technologies. If we are unable to enter into the desired agreements, if the agreements do not yield the intended results or if the agreements terminate, we may need to find alternative approaches to such technology needs. If any of these occur, the development and commercialization of one or more drug candidates could be delayed, curtailed or terminated, any of which may adversely affect our business.

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. 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 revenues.

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 revenues would depend heavily on the success of the efforts of these third parties.

General Company Related Risks

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our by-laws may delay or prevent an acquisition of us or a change in our management. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a classified board of directors;
- a prohibition on actions by our stockholders by written consent; and
- limitations on the removal of directors.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Finally, these provisions establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions would apply even if the offer may be considered beneficial by some stockholders.

Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.

The stock market in general and the market prices for securities of biotechnology companies in particular have experienced extreme volatility that often has been unrelated or disproportionate to the operating performance of these companies. The trading price of our common stock has been, and is likely to continue to be, volatile. Furthermore, our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure to obtain FDA approval for the M-Enoxaparin or M356 ANDAs;
- other adverse FDA decisions relating to the M-Enoxaparin or M356 ANDAs, including an FDA decision to require additional data, including requiring clinical trials as a condition to M-Enoxaparin or M356 ANDA approval;
- FDA approval of other companies' ANDAs for generic versions of Lovenox or Copaxone;
- litigation involving our company or our general industry or both;
- a decision in favor of or against Teva Pharmaceutical Industries Ltd. in the current patent litigation matters, or a settlement related to either case;
- 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 with respect to our technology-enabled generic product candidates;
- 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 commercial quantities;
- failure of any of our product candidates, if approved, to achieve commercial success;
- 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 March 1, 2010, pursuant to our sublease agreements, we are leasing a total of approximately 78,500 square feet of office and laboratory space in one building in Cambridge, Massachusetts:

Property Location	Approximate Square Footage	Use	Lease Expiration Date
675 West Kendall Street Cambridge, Massachusetts 02142	78,500	Laboratory and Office	04/30/2011

Item 3. LEGAL PROCEEDINGS

On August 28, 2008, Teva Pharmaceuticals Industries Ltd. and related entities ("Teva") and Yeda Research and Development Co., Ltd. ("Yeda") filed suit against us, Sandoz and Novartis AG in the United Stated Federal District Court in 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 addition, Teva and Yeda alleged additional claims against Sandoz and Novartis AG seeking monetary, injunctive and declaratory relief for alleged misappropriation of trade secrets and unfair competition. On November 3, 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. Sandoz's answer also denied the allegations made by Teva and Yeda alleging misappropriation of trade secrets and unfair competition. In addition, we filed a counterclaim seeking damages for false patent marking under the applicable United States patent law. In November 2009, Teva amended its complaint to remove the trade secrets and unfair competition claims against Sandoz and Novartis AG. On December 23, 2009, near the close of discovery, we and Sandoz filed a motion for summary judgment as a matter of law in the case. On January 20, 2010, the court heard arguments from the parties on the meaning of certain disputed claim terms in a claim construction hearing (also known as a "Markman hearing"). There is no defined timeline for the judge to issue a decision on claim construction or on the summary judgment motion.

On December 10, 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and us for patent infringement related to certain non-Orange Book patents after Teva's motion to add those patents to the ongoing Paragraph IV litigation was denied. On January 7, 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.

While we intend to vigorously defend these suits and prosecute our counterclaims, and we believe that we can ultimately prove our case in court, litigation involves many risks and uncertainties, and each of these litigations could last a number of years. As a result, one or both of these litigations 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 any lawsuit with Teva Pharmaceutical Industries.

Item 4. RESERVED

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded publicly on the NASDAQ Global Market under the symbol "MNTA." The following table sets forth the high and low sale prices of our common stock for the periods indicated, as reported on the NASDAQ Global Market:

Quarter ended	High	Low
March 31, 2008	$12.49	$ 5.91
June 30, 2008	15.99	10.36
September 30, 2008	20.00	12.00
December 31, 2008	13.54	6.47
March 31, 2009	12.56	6.94
June 30, 2009	12.46	8.37
September 30, 2009	12.15	9.29
December 31, 2009	13.17	8.70

Holders

On February 26, 2010, the approximate number of holders of record of our common stock was 82.

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.

Sale of Unregistered Securities

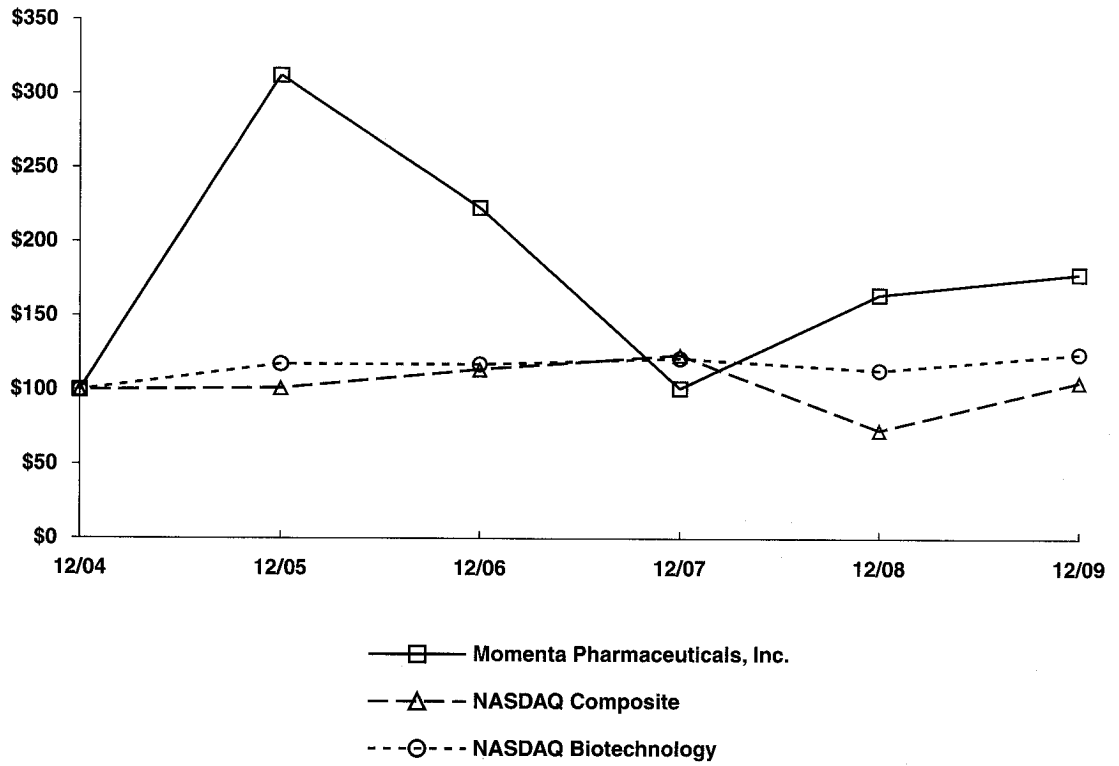
On August 4, 2009, we issued to Parivid, LLC ("Parivid"), a data integration and analysis services provider to us, 91,576 shares of our common stock in connection with an Amendment (the "Amendment") to that certain Asset Purchase Agreement, dated April 20, 2007, by and among us, Parivid and S. Raguram (the "Purchase Agreement"). Pursuant to the Purchase Agreement, we acquired certain of the assets and assumed certain of the liabilities of Parivid related to the acquired assets, 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. Pursuant to the Amendment, we agreed, among other things, as consideration for the completion and satisfaction of certain of the milestones that were achieved, agreed to pay Parivid $0.5 million cash and to issue 91,576 shares of our common stock. The issuance of shares of common stock described above was exempt from registration under the Securities Act of 1933 pursuant to an exemption from registration under Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder as not involving a public offering.

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, 2004 through December 31, 2009, 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



	12/31/04	12/31/05	12/31/06	12/31/07	12/31/08	12/31/09
Momenta Pharmaceuticals, Inc.	100.00	312.18	222.80	101.13	164.31	178.47
The NASDAQ Composite Index	100.00	101.33	114.01	123.71	73.11	105.61
The NASDAQ Biotechnology Index	100.00	117.54	117.37	121.37	113.41	124.58

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, 2009, 2008 and 2007 and the balance sheet data as of December 31, 2009 and 2008 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, 2006 and 2005 and the balance sheet data as of December 31, 2007, 2006 and 2005 are derived from our audited financial statements, which are not included herein. Historical results are not necessarily indicative of future results. See the notes to the consolidated financial statements for an explanation of the method used to determine the number of shares used in computing basic and diluted net loss per common 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,				
	2009	2008	2007	2006	2005
	(In thousands, except per share information)				
Statements of Operations Data:					
Collaboration revenue	$ 20,249	$ 14,570	$ 21,561	$ 15,999	$ 13,011
Operating expenses:					
Research and development	60,612	55,301	69,899	46,916	23,710
General and administrative	23,800	24,591	28,219	28,466	14,059
Total operating expenses	84,412	79,892	98,118	75,382	37,769
Loss from operations	(64,163)	(65,322)	(76,557)	(59,383)	(24,758)
Interest income	825	3,483	8,484	7,974	3,353
Interest expense	(570)	(798)	(808)	(504)	(257)
Other expense	(104)	—	—	—	—
Net loss	$(64,012)	$(62,637)	$(68,881)	$(51,913)	$(21,662)
Basic and diluted net loss per share	$ (1.60)	$ (1.74)	$ (1.93)	$ (1.62)	$ (0.79)
Shares used in computing basic and diluted net loss per share	40,056	35,960	35,639	32,103	27,283

	As of December 31,				
	2009	2008	2007	2006	2005
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 21,934	$ 55,070	$ 33,038	$ 22,351	$ 25,890
Marketable securities	73,716	53,461	102,899	168,914	130,364
Working capital	85,753	93,483	125,293	185,299	155,661
Total assets	118,451	132,201	168,298	216,385	171,101
Total long-term obligations	7,949	13,604	7,971	7,057	2,996
Total liabilities	24,289	32,696	40,758	33,794	10,946
Accumulated deficit	(321,049)	(257,037)	(194,400)	(125,519)	(73,606)
Total stockholders' equity	$ 94,162	$ 99,505	$ 127,540	$ 182,591	$160,155

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

Momenta is a biotechnology company specializing in the characterization and process engineering of complex molecules. These complex molecules include proteins, polypeptides, and cell surface polysaccharides, like heparan-sulfate proteoglycans, or HSPGs. This results in a diversified product pipeline of complex generic, follow-on biologic, and novel drugs. These product opportunities are derived from our proprietary, innovative technology platform which we leverage to study the *structure* (thorough characterization of chemical components), *structure-process* (understand, design and control of manufacturing process), and *structure-activity* (understand and relate structure to biological and clinical activity) of complex molecule drugs.

Our complex generics and follow-on biologics activities are focused on building a thorough understanding of the *structure-process-activity* of complex molecule drugs to develop generic versions of marketed products. While we use a similar analytical and development approach across all of our product candidates, we tailor that approach for each specific product candidate. Our first objective is to apply our core analytical technology to thoroughly characterize the *structure* of the marketed product. By defining the chemical composition of multiple batches of the marketed product, we are able to develop an equivalence window which captures the inherent variability of the innovator's manufacturing process. Using this information we then build an extensive understanding of the *structure-process* relationship to thoroughly understand, design and control our manufacturing process to reproducibly manufacture an equivalent version of the marketed product. Where necessary, and as required by the U.S. Food and Drug Administration, or FDA, we will supplement an application with additional supportive *structure-activity* data (e.g., immunogenicity, pharmacodynamics). Our goal is to obtain FDA approval for and commercialize, either directly or with collaborative partners, complex generic and follow-on biologic products thereby providing high quality, effective, safe and affordable medicines to patients in need.

Our two most advanced complex generic product candidates target marketed products which were originally approved by the FDA as New Drug Applications, or NDAs. Therefore, we were able to access the existing generic regulatory pathway and submitted Abbreviated New Drug Applications, or ANDAs, for these generic candidates. ***M-Enoxaparin*** is designed to be a generic version of Lovenox® (enoxaparin sodium injection), a low molecular weight heparin, or LMWH, used to prevent and treat deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. Lovenox is a complex mixture of polysaccharide chains derived from naturally sourced heparin. Our second major generic product candidate is ***M356***, 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 complex mixture of polypeptide chains. With M356, we have extended our core characterization and process engineering capabilities from the characterization of complex polysaccharide mixtures to include the characterization of complex polypeptide mixtures. The ANDAs for both M-Enoxaparin and M356 are currently under FDA review.

In addition to our two complex generic product candidates, our follow-on biologics program further extends our proprietary technology platform to include the characterization and engineering of therapeutic protein products. By thoroughly characterizing these molecules, which are derived from natural or cell based manufacturing processes, we seek to gain a deeper understanding of the

relationship between the multiple steps involved in their manufacturing processes and the final product compositions. Our goal is to replicate our development approach with M-Enoxaparin and M356 and pursue the development and commercialization of multiple biogeneric (designated by FDA to be substitutable with the marketed product) or biosimilar (designated by FDA not to be directly substitutable with the marketed drug) products.

Our novel drug program leverages our characterization and process engineering capabilities to develop novel drugs by studying the *structure-activity* of complex mixtures. We are targeting our efforts to understand the relationship between structure and the biological and therapeutic activity of various complex molecule drug candidates. Our goal is to capitalize on the structural diversity and multi-targeting potential of these complex molecules to engineer novel drug candidates that we believe will meet key unmet medical needs in various diseases. While we believe that our capabilities to engineer improved and novel complex molecule drug candidates can be applied across several product categories with significant therapeutic potential, our most advanced efforts have been in the area of HSPGs. Our lead novel HSPG-based drug candidate, ***M118***, has been engineered to possess what we believe will be an improved therapeutic profile compared with other currently marketed products to support the treatment of ACS. ***M402***, our second novel HSPG-based drug candidate, is in early development as a potential anti-cancer agent. We also are seeking to discover and develop additional novel HSPG-based drugs, as well as improved and novel protein drug candidates by applying our technology to better understand the function of these complex molecules in biological processes.

Since our inception in May 2001, we have incurred annual net losses. As of December 31, 2009, we had an accumulated deficit of $321.0 million. We recognized net losses of $64.0 million, $62.6 million and $68.9 million for the years ended December 31, 2009, 2008 and 2007, respectively. We expect to incur substantial and increasing losses for the next several years as we develop our product candidates, expand our research and development activities and prepare for the potential commercial launch of our product candidates. 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 revenues to achieve and then maintain profitability.

Since our inception, we have had no revenues from product sales. Our revenues for the years ended December 31, 2009, 2008 and 2007 of $20.2 million, $14.6 million and $21.6 million, respectively, have been derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and primarily consist of amounts earned by us for reimbursement by Sandoz of research and development services and development costs for certain programs. To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates.

Financial Operations Overview

Revenue

We have not yet generated any revenue from product sales and are uncertain whether or not we will generate any revenue from the sale of products over the next several years. We have recognized, in the aggregate, $94.6 million of revenue from our inception through December 31, 2009. This revenue was derived entirely from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration. We will seek to generate revenue from a combination of research and development payments, profit sharing payments, milestone payments and royalties in connection with our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and similar future collaborative or strategic relationships. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of research and development and other payments received under our collaborative or strategic relationships, and the amount and timing of payments we receive upon the sale of our products, to the extent any are successfully commercialized.

Research and Development

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.

The following summarizes our primary research and development programs:

Development Programs

M-Enoxaparin

Our most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox, a complex drug consisting of a mixture of polysaccharide chains. Lovenox is a widely-prescribed LMWH used for the prevention and treatment of DVT and to support the treatment of ACS. Under our 2003 Sandoz Collaboration, we work with Sandoz exclusively to develop, manufacture and commercialize M-Enoxaparin in the U.S. and Sandoz is responsible for funding substantially all of the U.S.-related M-Enoxaparin development, regulatory, legal and commercialization costs. The total cost of development and commercialization, and the timing of M-Enoxaparin product launch, are subject to uncertainties relating to the development, regulatory approval and legal processes. Our collaborative partner, Sandoz, submitted ANDAs in its name to the FDA for M-Enoxaparin in syringe and vial forms seeking approval to market M-Enoxaparin in the United States.

The FDA is currently reviewing both of Sandoz's M-Enoxaparin ANDAs, including our manufacturing data and technology and characterization methodology. 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. The FDA has not requested human clinical trials at this time. However, there can be no assurances that the FDA will not require additional studies, including clinical studies, in the future and we cannot predict with a high degree of certainty the timing of any potential approval of the M-Enoxaparin ANDA by the FDA. We and Sandoz are also in active dialogue with the FDA regarding the sourcing and processing of our heparin supply. We and Sandoz are working together to prepare for the commercialization of M-Enoxaparin, if and when approved, by advancing manufacturing, supply chain, and sales and marketing objectives.

M356

M356 is designed to be a generic version of Copaxone, a complex drug consisting of a mixture of polypeptide chains. Copaxone is indicated for reduction of the frequency of relapses in patients with RRMS. Multiple sclerosis is a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. In North America, Copaxone is marketed by Teva Neuroscience LLC, a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd. In Europe, Copaxone is marketed by Teva Pharmaceutical Industries Ltd. and Sanofi-Aventis.

In December 2007, our collaborative partner, Sandoz, submitted to the FDA an ANDA in its name containing a Paragraph IV certification seeking approval to market M356 in the United States. 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. 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.

M118

M118 is a novel anticoagulant that is a complex drug consisting of a mixture of polysaccharide chains. M118 was rationally designed to capture, in a single therapy, the positive attributes of both unfractionated heparin (reversibility, monitorability and broad inhibition of the coagulation cascade) and LMWH (adequate bioavailability and predictable pharmacokinetics to allow for convenient subcutaneous administration). We believe that M118 has the potential to provide baseline anticoagulant therapy for patients diagnosed with ACS who are medically managed and who may or may not require coronary intervention in order to treat their condition, as well as for patients diagnosed with stable angina who require a coronary intervention. We believe that the properties of M118 observed to date in both preclinical and clinical investigations continue to support the design hypothesis and may provide physicians with a more flexible treatment option than is currently available. ACS includes several diseases ranging from unstable angina, which is characterized by chest pain at rest, to acute myocardial infarction, or heart attack, which is caused by a complete blockage of a coronary artery. Currently, a majority of patients are initially medically managed with an anti-clotting agent, such as LMWH or unfractionated heparin, or UFH, in combination with other therapies. An increasing proportion of ACS patients are also proceeding to early intervention with procedures such as angioplasty or coronary artery bypass grafting, or CABG. Both angioplasty and CABG require anticoagulant therapy to prevent clot formation during and immediately following the procedure. M118 is designed to be a LMWH that could be used in multiple settings, including initial medical management, angioplasty or CABG.

In July 2006, we filed an Investigational New Drug Application, or IND, with the FDA for our M118 intravenous injection product and in October 2006 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. In June 2009, we completed a Phase 2a clinical trial to evaluate the feasibility of utilizing M118 intravenous injection as an anticoagulant in patients with stable coronary artery disease undergoing percutaneous coronary intervention. This trial, known as EMINENCE (Evaluation of M118 in Percutaneous Coronary Intervention), enrolled approximately 500 patients with stable coronary artery disease undergoing elective Percutaneous Coronary Intervention. Patients were randomly assigned to receive treatment with one of three doses of intravenous M118 or a standard dose of unfractionated heparin (UFH). The primary endpoint of the study was the combined incidence of clinical events defined as the composite of death, myocardial infarction, repeat revascularization, and stroke (over thirty days); incidence of bleeding and thrombocytopenia (over the first 24 hours); and bailout use of glycoprotein IIb/IIIa inhibitors and catheter thrombus (during the procedure). The primary analysis in the study provided evidence of non-inferiority of the combined M118 group (combining all three doses) as compared to the UFH group within the parameters of the prospectively defined analysis. The observed incidence of the primary endpoint was lower in all M118 treatment groups than in the UFH group; however it should be noted that the study was not designed or powered to detect statistically significant differences between treatments. The incidence of serious and non-serious adverse events was comparable in all treatment groups.

In March 2007, we submitted an IND for our M118 subcutaneous injection product, and in May 2007 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. These trials have been completed.

We believe that the results of clinical trials conducted to date support continuing the evaluation of M118 in patients diagnosed with ACS who are medically managed with or without an intervention. We are seeking a collaborative partner to finance and support the further clinical development of M118. We will not start additional clinical trials until we have a partner or funding available, but we do remain committed to the product and its continued development.

M402

M402 is our next most advanced novel HSPG-based product candidate and is engineered to have potent anti-cancer properties and low anticoagulant activity. HSPGs are complex molecules present in the tumor microenvironment which play a role in the conversion of normal cells into cancerous cells, and present growth factors, cytokines, and chemokines necessary for tumor cell growth, migration, and survival. M402 is designed to exploit this biology. Data from preclinical studies have shown that M402 has the potential to modulate angiogenesis and tumor metastasis through a variety of HSPG-binding proteins. We currently have plans to advance M402 into human clinical trials in the first half of 2011.

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, legal, accounting, investor relations, business development and human resource functions. Other costs include facility and insurance costs not otherwise included in research and development expenses and professional fees for legal and accounting services and other general expenses.

Results of Operations

Years Ended December 31, 2009, 2008 and 2007

Revenue

Revenue for 2009 was $20.2 million, compared with $14.6 million for 2008 and $21.6 million for 2007. Revenue for the year ended December 31, 2009 consists of amounts earned by us under our 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs and amounts earned by us under our 2006 Sandoz Collaboration for amortization of the equity premium, reimbursement of research and development services and reimbursement of development costs. Revenue increased $5.6 million from 2008 to 2009 due primarily to a $6.4 million increase in reimbursable process engineering activities associated with our M356 program and a $0.6 million increase in reimbursable expenses associated with our M-Enoxaparin program, primarily for development services related to the ANDA review process. These increases were offset by a $1.3 million decrease in reimbursable expenses associated with our M178 program, as planned development activities on the M178 program were completed.

Revenue decreased $7.0 million from 2007 to 2008 due primarily to a decrease in reimbursable expenses associated with the development of M-Enoxaparin. The manufacturing costs for pre-launch inventory for M-Enoxaparin are incurred directly by Sandoz and therefore do not flow through our collaborative revenues.

Research and Development

Research and development expense for 2009 was $60.6 million, compared with $55.3 million in 2008 and $69.9 million in 2007. The increase of $5.3 million, or 10%, from 2008 to 2009 principally resulted from: increases of $4.6 million in manufacturing, process development and third-party research costs primarily in support of our M356 program; $1.3 million in stock-based compensation expense; $1.0 million in depreciation and facility related expense; $0.6 million in personnel and related costs; and $0.3 million in consultant costs. These increases were offset by decreases of $1.5 million in clinical development costs associated with the completion of the Phase 2a clinical trial for our M118 program, a $0.5 million credit to research and development expense as a result of a revision to an accrued milestone liability and a decrease of $0.5 million in laboratory supplies.

The decrease of $14.6 million, or 21%, from 2007 to 2008 principally resulted from decreases of: $13.8 million in process development, manufacturing and third-party research costs in support of our development programs, principally our M-Enoxaparin and M356 programs; $1.7 million in stock-based

compensation expense; $0.7 million in-process research and development expense related to the 2007 Parivid asset purchase; and $0.5 million in consultant costs. These decreases were offset by increases of $1.1 million in personnel and related costs, $0.7 million in laboratory expenses and $0.7 million in depreciation expense.

The lengthy process of securing FDA approvals 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 research and development programs for the years ended December 31, 2009, 2008, and 2007, and shows the total external costs incurred by us for each of our major research and development projects. The table excludes costs incurred by our collaboration partner on such major research and development projects. We do not maintain or evaluate, and therefore do not allocate, internal research and development costs on a project-by-project basis. Consequently, we do not analyze internal research and development costs by project in managing our research and development activities.

Research and Development Expense (in thousands)	2009	2008	2007	Project Inception to December 31, 2009
Development programs (Status)				
M-Enoxaparin (ANDA Filed)	$ 4,239	$ 3,855	$13,078	$44,102
M356 (ANDA Filed)	10,670	4,401	8,105	26,675
M118 (Phase 2a)	5,641	9,886	10,945	35,269
Other development programs	1,969	589	442	
Discovery programs	455	664	997	
Research and development internal costs	37,638	35,906	36,332	
Total research and development expense	$60,612	$55,301	$69,899	

The increase of $0.4 million in external expenditures related to our M-Enoxaparin program from 2008 to 2009 was primarily due to increased development services related to the ANDA review process. The increase in external expenditures on our M356 program of $6.3 million from 2008 to 2009 was due to increased process development, manufacturing costs and third-party research expenses. The decrease of $4.2 million in external expenditures on our M118 program from 2008 to 2009 was due to the completion of our Phase 2a clinical trial in June 2009.

The decrease of $9.2 million in external expenditures related to our M-Enoxaparin program from 2007 to 2008 was primarily due to lower manufacturing activity and a shift to commercial activity being contracted directly with Sandoz. The decrease of $3.7 million in external expenditures related to our M356 program from 2007 to 2008 was primarily related to the timing of drug process work and the investment required to support the ANDA filing at the end of 2007. The decrease of $1.0 million in external expenditures on our M118 program from 2007 to 2008 was primarily attributable to start-up costs incurred in 2007 for the Phase 2a clinical trial.

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 $1.7 million from 2008 to 2009 was due to additional research and development headcount and related costs in support of our development programs.

General and Administrative

General and administrative expense for the year ended December 31, 2009 was $23.8 million, compared to $24.6 million in 2008 and $28.2 million in 2007. General and administrative expense decreased by $0.8 million, or 3%, from 2008 to 2009 primarily due to a decrease of $1.1 million in professional fees due to a reduction in legal and consulting activities, offset by an increase of $0.3 million in stock-based compensation expense. General and administrative expense decreased by $3.6 million, or 13%, from 2007 to 2008 due to a decrease of $1.8 million in stock-based compensation expense primarily due to a revision of the expected vesting date on certain performance-based restricted stock awards and a decrease of $1.8 million in professional fees due to a reduction in legal and consulting activities.

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 research and development activities.

Interest Income

Interest income was $0.8 million, $3.5 million and $8.5 million for the years ended December 31, 2009, 2008 and 2007, respectively. The decrease of $2.7 million from 2008 to 2009 and the decrease of $5.0 million from 2007 to 2008 were primarily due to lower average investment balances and lower interest rates.

Interest Expense

Interest expense was $0.6 million, $0.8 million and $0.8 million for the years ended December 31, 2009, 2008 and 2007, respectively. The decrease of $0.2 million from 2008 to 2009 was primarily due to the completion of a repayment schedule on our equipment line of credit during 2009.

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 and borrowings from our lines of credit and capital lease obligations. Since our inception, we have received net proceeds of $45.4 million from the issuance of redeemable convertible preferred stock. In June 2004, we completed our initial public offering and raised net proceeds of $35.3 million at which time all shares of preferred stock converted to common stock. In July 2005, we completed a follow-on public offering and raised net proceeds of $122.3 million. In September 2006, we received net proceeds of $74.9 million from Novartis Pharma AG's purchase of 4,708,679 shares of our common stock in connection with our 2006 Sandoz Collaboration. In December 2008 and September 2009, we completed public offerings and raised net proceeds of $24.1 million and $46.8 million, respectively. As of December 31, 2009, we have received a cumulative total of $89.3 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. 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 2011. 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, 2009, we had $95.7 million in cash, cash equivalents and marketable securities. In addition, we also hold $1.8 million in restricted cash which serves as collateral for a letter of credit

related to our facility lease. During the years ended December 31, 2009, 2008 and 2007, our operating activities used $55.3 million, $48.4 million and $56.3 million, respectively. The use of cash for operating activities generally approximates our net loss adjusted for non-cash items and changes in operating assets and liabilities. For the year ended December 31, 2009, non-cash items include stock based compensation of $10.8 million and depreciation and amortization of $4.8 million. 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 $6.9 million and resulted from: a decrease in accounts receivable of $0.5 million, due to the timing of cash receipts from Sandoz; 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 batches; 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 M118 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.

For the year ended December 31, 2008, our net loss adjusted for non-cash items was $51.2 million. In addition, the net change in our operating assets and liabilities provided $2.7 million and resulted from: a decrease in accounts receivable of $0.3 million, due to the timing of cash receipts from Sandoz; a decrease in unbilled collaboration revenue of $6.7 million, resulting from decreased manufacturing and research costs for our M-Enoxaparin program; a decrease in prepaid expenses and other current assets of $0.7 million, related to declining investment balances and lower interest rates; a decrease in accounts payable of $3.6 million, due to the payment of manufacturing and research costs for our M-Enoxaparin program; a decrease in deferred revenue of $2.2 million, due primarily to the amortization of the $13.6 million equity premium paid by Novartis in connection with the 2006 Sandoz Collaboration; and an increase in accrued expenses of $0.8 million, due to the timing of vendor payments.

For the year ended December 31, 2007, our net loss adjusted for non-cash items was $57.7 million. In addition, the net change in our operating assets and liabilities provided $1.4 million and resulted from: increases in accounts receivable of $0.7 million and unbilled collaboration revenue of $4.3 million, due to timing of cash receipts from Sandoz and an increase in billable activities; a decrease in restricted cash of $2.9 million due to the cancellation of a letter of credit for a terminated sublease; an increase in accounts payable of $4.8 million, resulting from increased manufacturing and research costs for our programs; and a decrease in deferred revenue of $1.3 million, due primarily to the amortization of the $13.6 million equity premium.

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. Net cash provided by investing activities was $48.2 million for the year ended December 31, 2008. During 2008, we used $120.5 million of cash to purchase marketable securities, and we received $172.1 million from sales and maturities of marketable securities. Net cash provided by investing activities was $60.9 million for the year ended December 31, 2007. During 2007, we used $242.5 million of cash to purchase marketable securities, offset by cash provided of $314.7 million in maturities of marketable securities. During the years ended December 31, 2009, 2008 and 2007, we used $1.7 million, $3.4 million and $8.8 million, respectively, to purchase laboratory equipment and leasehold improvements.

Net cash provided by financing activities was $44.4 million, $22.3 million and $6.1 million for the years ended December 31, 2009, 2008 and 2007, respectively. 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. During 2008, we received net proceeds of $24.1 million from our public offering of common stock and $1.2 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of $2.4 million on our line of credit and capital lease agreement obligations and $0.6 million on financed leasehold improvements related to our corporate facility. During 2007, we borrowed $4.2 million on our equipment lease agreement, recovered $3.7 million in property and equipment from the assignment of a sublease, received proceeds of $0.9 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These borrowings and proceeds were offset by principal payments of $2.1 million on our line of credit and capital lease agreement obligations and payments of $0.6 million on financed leasehold improvements.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2009:

Contractual Obligations (in thousands)	Total	2010	2011 through 2012	2013 through 2014	After 2014
License maintenance obligations	$ 788	$ 158	$ 315	$315	*
Capital lease obligations	4,443	2,626	1,817	—	$—
Operating lease obligations	4,930	3,650	1,280	—	—
Total contractual obligations	$10,161	$6,434	$3,412	$315	$—

* After 2014, the annual obligations, which extend indefinitely, are approximately $0.2 million per year.

Parivid Milestone Payment

On August 4, 2009, we entered into an Amendment to the Asset Purchase Agreement, or the Purchase Agreement, dated April 20, 2007, with Parivid, LLC, a data integration and analysis services provider, and S. Raguram. 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 were structured to include (i) potential payments of no more than $2.0 million in cash if certain milestones were 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.

Pursuant to the Amendment, 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.

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

We recognize revenue from research and development collaboration agreements. We record revenue on an accrual basis as it is earned and when amounts are considered collectible. Revenue received in advance of performance obligations or in cases where we have a continuing obligation to perform services are deferred and recognized over the performance period. When we are required to defer revenue, the period over which such revenue is recognized is based on estimates by management and may change over the course of the performance period. At the inception of a collaboration agreement, we estimate the term of our performance obligation based on our development plans and our estimate of the regulatory review period. The development plans generally include designing a manufacturing process to make the drug product, 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. Each reporting period we reassess our remaining performance obligations under the applicable collaboration arrangement by considering the time period over which any remaining development and related services to be provided prior to obtaining regulatory approval are expected to be completed. Changes in our estimate could occur due to changes in our development plans or due to changes in regulatory or legal requirements. We have deferred upfront payments of $0.6 million and $13.6 million in connection with our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, respectively. Such upfront payments are being recognized over our estimated period of performance obligation, which is approximately five and a half years and six years, respectively, from the applicable collaboration inception date. The deferral period for the upfront payment associated with our 2003 Sandoz Collaboration was completed during 2008.

We recognize payments for the achievement of substantive, at risk milestones that represent the culmination of a separate earnings process as revenue when due or paid.

Cash and Cash Equivalents

We consider 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, 2009.

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 2009, 2008 or 2007. Realized gains and losses are reported in interest income on a specific identification basis. During the year ended December 31, 2008, we recorded realized gains on marketable securities of $47,000. There were no realized gains or losses on marketable securities during the years ended December 31, 2009 or 2007.

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.

Accrued Expenses

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

Stock-Based Compensation

We recognize the fair value of stock-based compensation in our statement of operations. Stock-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 stock-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 stock-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. In December 2009, we revised the implicit service period for certain performance-based restricted stock awards due to a change in the expected vesting date. The impact of this change in estimate on our net loss and net loss per share was immaterial for the year ended December 31, 2009.

For the years ended December 31, 2009, 2008 and 2007, we recognized total stock-based compensation expense of $10.8 million, $9.2 million and $12.7 million, respectively. As of December 31, 2009, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $8.5 million, including estimated forfeitures, which will be amortized over the weighted-average remaining requisite service periods of 2.1 years. As of December 31, 2009, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $3.1 million, which will be amortized over the weighted-average remaining requisite service periods of approximately 1.1 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.

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 U.S. 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 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, 2009, 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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 12, 2010

Momenta Pharmaceuticals, Inc.

Consolidated Balance Sheets

	December 31, 2009	December 31, 2008
	(In thousands, except per share amounts)	
Assets		
Current assets:		
Cash and cash equivalents	$ 21,934	$ 55,070
Marketable securities	73,716	53,461
Accounts receivable	—	455
Unbilled collaboration revenue	4,750	2,372
Prepaid expenses and other current assets	1,693	1,217
Total current assets	102,093	112,575
Property and equipment, net of accumulated depreciation	11,795	14,725
Intangible assets, net	2,785	3,111
Restricted cash	1,778	1,778
Other assets	—	12
Total assets	$ 118,451	$ 132,201
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,225	$ 5,578
Accrued expenses	6,114	6,744
Deferred revenue	2,850	2,150
Line of credit obligations	—	17
Capital lease obligations	2,344	1,846
Lease financing liability	737	687
Deferred rent	70	70
Other current liabilities	—	2,000
Total current liabilities	16,340	19,092
Deferred revenue, net of current portion	5,913	8,063
Capital lease obligations, net of current portion	1,729	4,427
Lease financing liability, net of current portion	258	995
Other long term liabilities	49	119
Total liabilities	24,289	32,696
Commitments and contingencies (Note 13)		
Stockholders' Equity:		
Preferred stock, $0.01 par value; 5,000 shares authorized at December 31, 2009 and 2008, 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, 2009 and 2008, 44,627 and 39,691 shares issued and outstanding at December 31, 2009 and 2008, respectively	4	4
Additional paid-in capital	415,214	356,124
Accumulated other comprehensive income (loss)	(7)	414
Accumulated deficit	(321,049)	(257,037)
Total stockholders' equity	94,162	99,505
Total liabilities and stockholders' equity	$ 118,451	$ 132,201

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

Momenta Pharmaceuticals, Inc.

Consolidated Statements of Operations

	Year Ended December 31,		
	2009	2008	2007
	(In thousands, except per share amounts)		
Collaboration revenue	$ 20,249	$ 14,570	$ 21,561
Operating expenses:			
Research and development*	60,612	55,301	69,899
General and administrative*	23,800	24,591	28,219
Total operating expenses	84,412	79,892	98,118
Loss from operations	(64,163)	(65,322)	(76,557)
Other income (expense):			
Interest income	825	3,483	8,484
Interest expense	(570)	(798)	(808)
Other expense	(104)	—	—
Net loss	$(64,012)	$(62,637)	$(68,881)
Basic and diluted net loss per share	$ (1.60)	$ (1.74)	$ (1.93)
Shares used in computing basic and diluted net loss per share	40,056	35,960	35,639
* Includes stock-based compensation as follows:			
Research and development	$ 4,377	$ 3,124	$ 4,792
General and administrative	$ 6,378	$ 6,090	$ 7,895

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

Momenta Pharmaceuticals, Inc.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE LOSS

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balances at December 31, 2006	36,098	$ 4	$308,061	$ 45	$(125,519)	$182,591
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	143	—	856	—	—	856
Issuance of restricted stock	248	—	—	—	—	—
Stock-based compensation expense for employees	—	—	12,682	—	—	12,682
Stock-based compensation expense for non-employees	—	—	5	—	—	5
Unrealized gain on marketable securities	—	—	—	287	—	287
Net loss	—	—	—	—	(68,881)	(68,881)
Comprehensive loss	—	—	—	—	—	(68,594)
Balances at December 31, 2007	36,489	$ 4	$321,604	$ 332	$(194,400)	$127,540
Issuance of common stock in public offering	2,800	—	24,140	—	—	24,140
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	193		1,166		—	1,166
Issuance of restricted stock	252	—	—	—	—	—
Cancellation of restricted stock	(43)	—	—	—	—	—
Stock-based compensation expense for employees	—	—	9,214	—	—	9,214
Unrealized gain on marketable securities	—	—	—	82	—	82
Net loss	—	—	—	—	(62,637)	(62,637)
Comprehensive loss	—	—	—	—	—	(62,555)
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	—	—	—	—	—
Stock-based compensation expense for employees	—	—	10,658	—	—	10,658
Stock-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

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

Momenta Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2009	2008	2007
	(In thousands)		
Cash Flows from Operating activities:			
Net loss	$ (64,012)	$ (62,637)	$ (68,881)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,470	3,975	3,308
Stock-based compensation expense	10,755	9,214	12,687
Loss on disposal of assets	114	7	92
Accretion of discount on investments	(57)	(2,047)	(5,907)
Realized gain on sales of marketable securities	—	(47)	—
Charge for in-process research and development	—	—	737
Amortization of intangibles	326	384	268
Changes in operating assets and liabilities:			
Accounts receivable	455	292	(747)
Unbilled collaboration revenue	(2,378)	6,665	(4,310)
Prepaid expenses and other current assets	(476)	767	85
Restricted cash	—	—	2,907
Other assets	12	12	12
Accounts payable	(1,353)	(3,554)	4,821
Accrued expenses	(630)	771	187
Deferred rent	(70)	(70)	(312)
Deferred revenue	(1,450)	(2,179)	(1,283)
Other current liabilities	(1,000)	—	—
Other long term liabilities	—	26	—
Net cash used in operating activities	(55,294)	(48,421)	(56,336)
Cash Flows from Investing activities:			
Purchase of intangible assets	—	—	(2,500)
Purchases of marketable securities	(110,194)	(120,527)	(242,526)
Proceeds from maturities of marketable securities	89,575	163,800	314,735
Purchase of property and equipment	(1,654)	(3,411)	(8,817)
Sales of marketable securities	—	8,341	—
Net cash (used in) provided by investing activities	(22,273)	48,203	60,892
Cash Flows from Financing activities:			
Proceeds from public offering of common stock, net of issuance costs	46,766	24,140	—
Proceeds from issuance of common stock under stock plans	569	1,166	856
Payments on financed leasehold improvements	(687)	(639)	(596)
Principal payments on line of credit	(17)	(721)	(883)
Proceeds from capital lease obligations	—	—	4,199
Principal payments on capital lease obligations	(2,200)	(1,696)	(1,169)
Proceeds from assignment of sublease, net of recovery of rent expense	—	—	3,724
Net cash provided by financing activities	44,431	22,250	6,131
(Decrease) increase in cash and cash equivalents	(33,136)	22,032	10,687
Cash and cash equivalents, beginning of period	55,070	33,038	22,351
Cash and cash equivalents, end of period	$ 21,934	$ 55,070	$ 33,038
Supplemental Cash Flow Information:			
Cash paid for interest	$ 570	$ 798	$ 808
Non Cash Transactions:			
Accrued milestone payments to Parivid	$ —	$ —	$ 2,000
Issuance of common stock for payment of milestone	$ 1,000	$ —	$ —

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

1. The Company

Business

Momenta Pharmaceuticals, Inc. (the "Company" or "Momenta") was incorporated in the state of Delaware in May, 2001 and began operations in early 2002. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the 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 research collaborations with pharmaceutical companies.

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 financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates.

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, 2009.

Fair Value Measurements

Effective January 1, 2009, the Company adopted a newly issued accounting standard for fair value measurements of all nonfinancial assets and nonfinancial liabilities not recognized or disclosed at fair value in the financial statements on a recurring basis. The adoption of the accounting standard for these assets and liabilities did not have a material impact on the Company's financial position or results of operations.

Effective January 1, 2008, the Company adopted a standard for fair value measurements for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. The adoption of this guidance did not have an impact on the Company's financial position or results of operations.

On a recurring basis, the Company measures certain financial assets and financial liabilities at fair value based upon quoted market prices, where available. Where quoted market prices or other observable inputs are not available, the Company applies valuation techniques to estimate fair value. The accounting standards for fair value measurements establish a three-level valuation hierarchy for

disclosure of 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—inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2—inputs to the valuation methodology are other observable inputs, including quoted prices for similar assets and liabilities in active or non-active markets, inputs other than quoted prices that are observable for the asset or liability, and inputs that are not directly observable, but are corroborated by the observable market data.
- Level 3—inputs to the valuation methodology are unobservable for the asset or liability.

A Level 1 classification is applied to any asset that has a readily available quoted price from an active market where there is significant transparency in the executed / quoted price. A Level 2 classification is applied to assets whose fair values are determined using quoted prices in active markets for similar assets or inputs other than quoted prices that are observable for the asset.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, unbilled collaboration revenue, other current assets, accounts payable and accrued expenses, approximate fair value due to their short-term maturities. The carrying amounts for the line of credit and 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 and marketable securities.

The Company invests its cash in bank deposits, money market accounts, corporate debt securities, commercial paper and U.S. 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

Marketable Debt 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 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 consolidated statements of operations. There were no charges taken for other-than-temporary declines in fair value of marketable securities in 2009, 2008 or 2007. Realized gains and losses are reported in interest income on a specific identification basis. During the year ended December 31, 2008, the Company recorded realized gains on marketable securities of $47,000. There were no realized gains or losses on marketable securities during the years ended December 31, 2009 or 2007.

Other-than-Temporary Impairments

In April 2009, the Company implemented a newly issued accounting standard which provides guidance for the recognition, measurement and presentation of other-than-temporary impairments. This

newly issued standard amended the other-than-temporary impairment model for debt securities and requires additional disclosures regarding the calculation of credit losses and the factors considered in reaching a conclusion that an investment is other-than-temporarily impaired.

Under the new accounting standards, an other-than-temporary impairment must be recognized through earnings if an investor has the intent to sell the debt security or if it is more likely than not that the investor will be required to sell the debt security before recovery of its amortized cost basis. However, even if an investor does not expect to sell a debt security, expected cash flows to be received must be evaluated to determine if a credit loss has occurred. In the event of a credit loss, only the amount associated with the credit loss is recognized in income. The amount of losses relating to other factors, including those resulting from changes in interest rates, are recorded in accumulated other comprehensive income (loss). The Company did not record any impairment charges related to marketable securities during the years ended December 31, 2009, 2008 or 2007.

Unbilled Collaboration Revenue

Unbilled collaboration revenue represents amounts owed from one collaborative partner at December 31, 2009 and December 31, 2008. 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 results 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 undiscounted future cash flows of such assets or businesses. No impairment charges have been recognized through December 31, 2009.

Revenue Recognition

The Company receives revenue from research and development collaboration agreements. Under the terms of collaboration agreements entered into by the Company, the Company may 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.

Revenue from non-refundable, up-front license fees are recognized on a straight-line basis over the contracted or estimated period of performance, which is typically the development term. Research and development funding is recognized as earned over the period of effort.

Any milestone payments are recognized as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone and (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payment is deferred and recognized as revenue over the estimated remaining period of performance under the contract as the Company completes its performance obligations. Royalty and/or profit-share revenue, if any, is recognized based upon actual and estimated net sales of licensed products in licensed territories as provided by the licensee and in the period the sales occur. The Company has not recognized any milestone, royalty or profit-share revenue to date.

Research and Development

Research and development costs are expensed as incurred. Research and development costs include wages, benefits, facility and other research-related overhead expenses, as well as license fees, clinical trial costs and contracted research and development activities. Nonrefundable 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.

Stock-Based Compensation

The Company recognizes the fair value of stock-based compensation in its statement of operations. Stock-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 stock-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. The Company issues new shares to satisfy stock option exercises, the issuance of restricted stock and stock issued 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 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 concluded that a blended volatility rate based upon the most recent four-and-one-half year period of its own historical performance, as well as the implied volatilities of its own currently traded options, appropriately reflects the expected volatility of its stock going forward. 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 updates these assumptions as needed to reflect recent historical data. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

The Company applies an estimated forfeiture rate to current period expense to recognize stock-based compensation expense only for those 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 stock-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.

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 Loss

Accumulated other comprehensive income (loss) as of December 31, 2009 and December 31, 2008 consists entirely of unrealized gains and losses on available-for-sale securities. Comprehensive loss for the years ended December 31, 2009, 2008 and 2007 was $64.4 million, $62.6 million and $68.6 million, respectively.

Net Loss Per Share

The Company computes net loss per share by dividing net loss by the weighted-average number of common shares outstanding during the reporting period. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common stock equivalent shares consist of the incremental common shares issuable upon the exercise of stock options and warrants. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per common share is the same in all periods. The total number of shares excluded from the calculations of historical diluted net loss per share, due to their antidilutive effect, was 5,515,593, 4,938,537 and 3,981,601 for the years ended December 31, 2009, 2008 and 2007, respectively, prior to the application of the treasury stock method.

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 product candidates. All of the Company's revenues through December 31, 2009 have come from one collaborative partner.

Subsequent Events

The Company has evaluated events occurring after the date of the consolidated financial statements for potential recognition or disclosure in its financial statements. The Company did not identify any subsequent events requiring adjustment to the accompanying consolidated financial statements (recognizable subsequent events) or disclosure (unrecognized subsequent events).

Recently Issued Accounting Standards

In October 2009, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2009-13, *Multiple-Deliverable Revenue Arrangements (Topic 605)*, or ASU 2009-13. ASU 2009-13 amends existing revenue recognition accounting pronouncements that are currently within the scope of Accounting Standards Codification (ASC) Subtopic 605-25. The consensus in ASU 2009-13 provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The present standard requires that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. In addition, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This new approach is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company does not believe this standard will have a material impact on its financial position or results of operations.

3. Fair Value Measurements

Summary of Assets and Liabilities Recorded at Fair Value

The tables below present information about the Company's assets that are measured at fair value on a recurring basis as of December 31, 2009 and 2008 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.

Financial assets classified as Level 1 and 2 have been initially valued at the transaction price and subsequently valued based on changes in quoted market prices or based on prices provided by third party pricing services. The pricing services use many observable market inputs to determine value, including reportable trades, benchmark yields, broker/dealer quotes, bids and offers. The Company validates the prices provided by its third party pricing services and did not adjust or override any fair value measurements as of December 31, 2009 and 2008.

The following tables set forth the Company's financial assets and liabilities that were recorded at fair value (in thousands):

Description	December 31, 2009	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$20,201	$19,700	$ 501	$—
Marketable securities:				
U.S. Treasury obligations	15,181	15,181	—	—
U.S. Government-sponsored enterprise obligations	58,535	—	58,535	—
Total	$93,917	$34,881	$59,036	$—

Description	December 31, 2008	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 50,506	$50,506	$ —	$—
Marketable securities:				
Commercial paper obligations	23,497	—	23,497	—
U.S. Government-sponsored enterprise obligations	29,964	—	29,964	—
Total	$103,967	$50,506	$53,461	$—

The following table summarizes the Company's cash, cash equivalents and marketable securities as of December 31, 2009 and 2008 (in thousands):

December 31, 2009	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$21,433	$—	$ —	$21,433
U.S. Treasury obligations due in one year or less	15,184	1	(4)	15,181
U.S. Government-sponsored enterprise obligations due in one year or less	59,040	11	(15)	59,036
Total	$95,657	$12	$(19)	$95,650
Reported as:				
Cash and cash equivalents	$21,934	$—	$ —	$21,934
Marketable securities	73,723	12	(19)	73,716
Total	$95,657	$12	$(19)	$95,650

December 31, 2008	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 55,070	$ —	$—	$ 55,070
Commercial paper obligations due in one year or less	23,349	148	—	23,497
U.S. Government-sponsored enterprise obligations due in one year or less	29,698	266	—	29,964
Total	$108,117	$414	$—	$108,531
Reported as:				
Cash and cash equivalents	$ 55,070	$ —	$—	$ 55,070
Marketable securities	53,047	414	—	53,461
Total	$108,117	$414	$—	$108,531

At December 31, 2009, 18 marketable securities were in an unrealized loss position for less than one year. At December 31, 2008, no marketable securities were in an unrealized loss position. The unrealized losses were caused by fluctuations in interest rates. The following table summarizes the aggregate fair value of these securities at December 31, 2009.

	2009	
(in thousands)	Aggregate Fair Value	Unrealized Losses
U.S. Treasury bonds due in one year or less	$ 9,122	$ (4)
U.S. Government-sponsored enterprise obligations due in one year or less	$22,857	$(15)

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, 2009 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.

4. Property and Equipment

At December 31, 2009 and 2008, property and equipment, net consists of the following (in thousands):

	2009	2008	Depreciable Lives
Computer equipment	$ 409	$ 382	3 years
Software	2,866	2,708	3 years
Office furniture and equipment	1,249	905	5 to 6 years
Laboratory equipment	8,160	6,170	7 years
Leasehold improvements	4,747	4,570	Shorter of asset life or lease term
Equipment purchased under capital lease obligations	8,405	10,061	3 to 7 years
Less: accumulated depreciation	(14,041)	(10,071)	
	$ 11,795	$ 14,725	

Depreciation and amortization expense, including amortization of assets recorded under capital leases, amounted to $4.5 million, $4.0 million and $3.3 million for the years ended December 31, 2009, 2008 and 2007, respectively.

5. Intangible Assets

At December 31, 2009 and 2008, intangible assets, net of accumulated amortization, are as follows (in thousands):

	Estimated Life	December 31, 2009 Gross Carrying Amount	December 31, 2009 Accumulated Amortization	December 31, 2008 Gross Carrying Amount	December 31, 2008 Accumulated Amortization
Core technology	12 years	$3,593	$(808)	$3,593	$(508)
Non-compete agreement	2 years	170	(170)	170	(144)
Total intangible assets		$3,763	$(978)	$3,763	$(652)

Amortization is computed using the straight-line method over the useful lives of the respective intangible assets. Amortization expense was $0.3 million, $0.4 million and $0.3 million during years ended December 31, 2009, 2008 and 2007, respectively.

The Company expects to incur amortization expense of appropriately $0.3 million per year for each of the next five years.

6. Restricted Cash

Restricted cash consists of $1.8 million designated as collateral for a letter of credit related to the lease of office and laboratory space. This balance will remain restricted during the 80-month lease term and the Company will continue to earn interest on the balance.

7. Accrued Expenses

At December 31, 2009 and 2008, accrued expenses consisted of the following (in thousands):

	2009	2008
Accrued compensation	$3,307	$3,208
Accrued contracted research costs	1,872	2,476
Accrued professional fees	570	773
Other	365	287
	$6,114	$6,744

8. 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 N.V. and Sandoz Inc. to jointly develop and commercialize M-Enoxaparin, a generic version of Lovenox®, a low molecular weight heparin. Sandoz N.V. later assigned its rights and obligations under the 2003 Sandoz Collaboration to Sandoz AG. Sandoz AG and Sandoz Inc. are collectively referred to as "Sandoz." Under the 2003 Sandoz Collaboration, the Company granted Sandoz the exclusive right to manufacture, distribute and sell M-Enoxaparin in the United States. The Company agreed to provide development and related services on a commercially reasonable basis, which includes developing a manufacturing process to make M-Enoxaparin, 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 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 approves the annual collaboration plan. Sandoz is responsible for commercialization activities and will exclusively distribute and market the product.

As compensation under the 2003 Sandoz Collaboration, the Company received a $0.6 million non-refundable up-front payment as reimbursement for certain specified vendor costs that were incurred prior to the effective date of the 2003 Sandoz Collaboration. The Company is paid at cost for external costs incurred for development and related activities and is paid for full time equivalents ("FTEs") performing development and related services. In addition, Sandoz will share profits with the Company, in the event there are no third party competitors marketing a Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration). Alternatively, in certain circumstances, if there are third party competitors marketing a Lovenox-Equivalent Product, Sandoz will pay royalties to the Company on net sales of injectable M-Enoxaparin. If certain milestones are achieved with respect to injectable M-Enoxaparin under certain circumstances, Sandoz will make payments to the Company, which would reach $55 million if all such milestones are achieved. A portion of the development expenses and certain legal expenses, which in the aggregate have exceeded a specified amount, will be 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 has not earned any milestones, royalties or profit-sharing amounts to date.

The Company recognized the $0.6 million non-refundable up-front payment as revenue on a straight-line basis over the estimated M-Enoxaparin development period of 5.5 years. The Company recognized revenue relating to this up-front payment of approximately $25,000 and $0.1 million for the years ended December 31, 2008 and 2007, respectively. The deferral period for the upfront payment associated with the 2003 Sandoz Collaboration was completed during 2008.

The Company recognizes revenue from FTE services and 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 (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 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 revenue relating to this paid premium of approximately $2.2 million for each of the years ended December 31, 2009 and 2008 and approximately $1.2 million for the year ended

December 31, 2007. Under the 2006 Sandoz Collaboration, the Company and Sandoz AG expanded the M-Enoxaparin geographic markets covered by the 2003 Sandoz Collaboration to include the European Union and further agreed to exclusively collaborate on the development and commercialization of three other follow-on and complex generic products for sale in specified regions of the world. In December 2008, the Company and Sandoz AG terminated the collaborative program with regard to one of the follow-on products, M249, primarily due to the commercial prospects for M249. In December 2009, the Company and Sandoz AG terminated the collaborative program with regard to the other follow-on product, M178. 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. For the remaining products under the collaboration, 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 approves the annual collaboration plan. 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. 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 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 if all milestones are achieved for the products remaining under collaboration. None of these payments, once received, is refundable and there are no general rights of return in the arrangement.

The Company recognizes revenue from FTE services and 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 are recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third party vendors for such development and related services, except with respect to any amounts due Sandoz for shared development costs, which are recorded on a net basis.

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.

In exchange for these rights, the Company paid M.I.T. a license issue fee, and pays annual license maintenance fees. The Company, upon commercialization, is also required to pay M.I.T. royalties on 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. M.I.T. and certain contributing individuals were also issued shares of the Company's common stock. The Company recorded license fee expense of $132,500, $107,500 and $82,500 related to these agreements in the years ended December 31, 2009, 2008 and 2007, respectively.

The Company must meet certain diligence requirements in order to maintain its licenses under the two agreements. Under the agreements, the Company must expend at least $1.0 to $1.2 million per year commencing in 2005 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. If the Company fails to meet its diligence obligations, M.I.T. may, as its sole remedy, convert the exclusive licenses granted to the Company under the amended and restated license agreement to non-exclusive licenses. Under the license agreement covering sequencing machines, M.I.T. has the right to treat the Company's failure to fulfill its diligence obligations as a material breach of the license agreement.

If, due to the Company's failure to meet diligence obligations, M.I.T. converts certain of the Company's exclusive licenses to non-exclusive, or if M.I.T. terminates one of the agreements, M.I.T. will honor the exclusive nature of the sublicense the Company granted to Sandoz so long as Sandoz both continues to fulfill its obligations to the Company under the 2003 Sandoz Collaboration, 2006 Sandoz Collaboration and license agreement and agrees to assume the Company's rights and obligations to M.I.T.

9. 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 stock-based awards to employees, officers, directors, consultants and advisors. At December 31, 2009, the Company was authorized to issue up to 9,420,445 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, 2010, the Company's Board of Directors increased the number of authorized shares by 1,974,303 shares. At December 31, 2009, the Company had 3,902,383 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 is awarded from time to time to key 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.

Stock-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, 2009, 2008 and 2007 was $10.8 million, $9.2 million and $12.7 million, respectively.

Stock-based compensation expense related to outstanding employee stock option grants was $7.6 million, $6.7 million and $7.0 million for the years ended December 31, 2009, 2008 and 2007, respectively.

During the year ended December 31, 2009, 683,165 stock options were granted, of which 517,815 were in connection with annual merit awards; the remainder were granted in conjunction with awards to the members of the board of directors and the hiring of new employees. The fair value of each option award was estimated on the date of grant using the Black-Scholes-Merton option-pricing model that uses the 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		
	2009	2008	2007	2009	2008	2007
Expected volatility	98%	83%	76%	95%	80%	74%
Expected dividends	—	—	—	—	—	—
Expected life (years)	6	6	6	0.5	0.5	0.5
Risk-free interest rate	2.6%	3.29%	4.7%	0.6%	3.0%	4.8%

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, 2009, the Company had 338,942 shares available for grant under the ESPP. The Company issued 44,737 shares of common stock to employees under the plan during the year ended December 31, 2009. 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 stock-based compensation expense equal to the fair value of the ESPP awards on a straight-line basis over the offering period. During the years ended December 31, 2009, 2008 and 2007, the Company recorded stock-based compensation expense of $0.3 million, $0.2 million and $0.2 million, respectively, with respect to the ESPP. At December 31, 2009, subscriptions were outstanding for an estimated 33,331 shares at a fair value of approximately $4.53 per share. The weighted average grant date fair value of the offerings during 2009, 2008 and 2007 was $4.88, $4.88 and $6.27 per share, respectively.

The following table presents stock option activity of the Company's stock plan for the year ended December 31, 2009:

	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, 2009	3,971	$11.27		
Granted	683	10.07		
Exercised	(31)	5.08		
Forfeited	(43)	12.81		
Expired	(66)	16.50		
Outstanding at December 31, 2009	4,514	$11.04	6.81	$12,932
Exercisable at December 31, 2009	3,125	$11.30	6.13	$ 9,135
Vested or expected to vest at December 31, 2009	4,395	$11.06	6.76	$12,595

The weighted average grant date fair value of options granted during 2009, 2008 and 2007 was $8.06, $6.92 and $7.90 per option, respectively. The total intrinsic value of options exercised during 2009, 2008 and 2007 was $0.2 million, $1.1 million and $1.0 million, respectively. At December 31, 2009, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $8.5 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.1 years. The total fair value of shares vested during 2009, 2008 and 2007 was $7.6 million, $6.2 million and $7.3 million, respectively.

Cash received from option exercises for 2009, 2008 and 2007 was $0.2 million, $0.8 million and $0.4 million, respectively. Due to the Company's net loss position, the tax benefit related to the tax deductions from option exercises was not realized in any of the periods presented.

Restricted Stock Awards

The Company has also made awards of restricted common stock to certain employees, officers and directors. During the year ended December 31, 2009, the Company awarded 169,350 shares of restricted common stock to certain employees and officers. Awards generally fully vest four years from the grant date, although certain awards have performance conditions, such as the commercial launch of M-Enoxaparin in the U.S.

In December 2009, the Company revised the implicit service period for certain performance-based restricted stock awards due to a change in the expected vesting date. The impact of this change in estimate on the Company's net loss and net loss per share was immaterial for the year ended December 31, 2009.

A summary of the status of nonvested shares of restricted stock as of December 31, 2009, 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, 2009	985	$16.89
Granted	169	10.43
Vested	(153)	9.12
Nonvested at December 31, 2009	1,001	$16.99

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of December 31, 2009 are summarized below:

Vesting Schedule	Nonvested Shares (in thousands)
Time-based	626
Performance-based	375
Nonvested at December 31, 2009	1,001

The total fair value of shares of restricted stock vested during 2009, 2008 and 2007 was $1.4 million, $144,000 and $64,000, respectively. The Company recorded stock-based compensation expense of $2.8 million, $2.3 million and $5.4 million related to outstanding restricted stock awards during 2009, 2008 and 2007, respectively. As of December 31, 2009, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $3.1 million, which is expected to be recognized over the weighted average remaining requisite service period of 1.1 years.

Stock Options Granted to Non-Employee Consultants

As of December 31, 2009, the Company had granted stock options to purchase 169,004 shares of common stock to consultants. These stock options were granted in exchange for consulting services to be rendered and vest over periods of up to four years. During 2007, 7,812 stock options were cancelled due to the termination of certain consulting agreements. During 2009 and 2008, 9,750 and 8,000 stock options expired, respectively. As of December 31, 2009, options to purchase an aggregate of 97,927 shares of common stock were exercisable. The Company recorded a stock-based compensation expense, using an accelerated method, of $97,000, zero and $5,000 during 2009, 2008 and 2007, respectively. The fair value of the options is estimated on the date of grant and subsequently revalued at each reporting period over their vesting period using the Black-Scholes-Merton option pricing model and assumptions including an expected life ranging from approximately six to nine years, volatility of approximately 98% and a risk free interest rate of approximately 3.0%.

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, 2009 and 2008, 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.

In connection with the 2006 Sandoz Collaboration, the Company sold 4,708,679 shares of common stock to Novartis Pharma AG for an aggregate purchase price of $75.0 million.

In December 2008, the Company raised $24.1 million in a public offering, net of expenses, from the sale and issuance of 2,800,000 shares of common stock. The price to the public was $9.00 per share.

In September 2009, the Company raised $46.8 million in a public offering, net of expenses, from the sale and issuance of 4,600,000 shares of common stock. The price to the public was $10.75 per share.

11. Income Taxes

A reconciliation of the federal statutory income tax provision to the Company's actual provision for the years ended December 31, 2009, 2008 and 2007 is as follows (in thousands):

	2009	2008	2007
Benefit at federal statutory tax rate	$(21,756)	$(21,304)	$(23,381)
State taxes, net of federal benefit	(4,014)	(3,927)	(4,319)
Change in valuation allowance	25,024	25,139	27,892
Stock-based compensation	1,169	662	810
Tax credits	(485)	(601)	(1,021)
Other	62	31	19
Income tax provision	$ —	$ —	$ —

At December 31, 2009, the Company had federal and state net operating loss carryforwards of $239.0 million and $236.0 million available, respectively, to reduce future taxable income and which will expire at various dates through 2029. Of this amount, approximately $4.7 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, 2009, federal and state research and development and other credit carryforwards were $5.6 million and $2.0 million, respectively, available to reduce future tax liabilities, and, which will expire at various dates beginning in 2017 through 2029.

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 are as follows (in thousands):

	December 31,	
	2009	2008
Deferred tax assets:		
Federal and state net operating losses	$ 91,979	$ 70,611
Research credits	4,936	4,827
Deferred compensation	12,149	9,942
Deferred revenue	3,442	4,011
Accrued expenses	229	201
Intangibles	283	437
Capital leases	1,991	3,124
Unrealized loss on marketable securities	2	—
Total deferred tax assets	115,011	93,153
Deferred tax liabilities:		
Depreciation	(2,434)	(3,754)
Unrealized gain on marketable securities	—	(144)
Total deferred tax liabilities	(2,434)	(3,898)
Valuation allowance	(112,577)	(89,255)
Net deferred tax assets	$ —	$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $23.3 million for the year ended December 31, 2009, primarily as a result of the current period loss.

The Company's practice has been and continues to be to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which was zero for the years ended December 31, 2009, 2008 and 2007.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for the years ended December 31, 2009 and 2008 (in thousands) in accordance with ASC 740-10 is as follows:

	2009	2008
Balance, beginning of year	$ 4,954	$4,425
Additions for tax positions related to the current year	311	649
Reductions of tax positions of prior years	(1,199)	(120)
Balance, end of year	$ 4,066	$4,954

As of December 31, 2009, the Company had $4.1 million of gross unrecognized tax benefits, $4.0 million of which, if recognized, would impact the Company's effective tax rate. As of December 31, 2008, the Company had $4.9 million of gross unrecognized tax benefits, $4.5 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 unused state research and development credits in 2009. As a result of that reassessment and recalculation, the carryforward amount was reduced by $1.2 million as well as the unrecognized tax benefits shown in the above rollforward.

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.

12. Line of Credit

In December 2004, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank (the "Bank"). Under the terms of the Loan Agreement, the Company was eligible to borrow up to an aggregate of $3.0 million solely for reimbursement of purchases of Eligible Equipment, as defined under the Loan Agreement. As of December 31, 2005, the Company had drawn $3.0 million against the Loan Agreement. The Company was not obligated to draw down any amounts under the Loan Agreement and any borrowings bear interest at the per annum rate of the U.S. Treasury note yield to maturity for a term equal to forty-two months plus 5%, which rate was fixed on the funding date for each advance under the Loan Agreement. Advances under the Loan Agreement were to be repaid over a forty-two month period commencing on the applicable funding date. To secure the payment and performance in full of the Company's obligations under the Loan Agreement, the Company granted to the Bank a continuing security interest in the Collateral, as such term is defined under the Loan Agreement and which essentially includes all Eligible Equipment and records relating thereto. As of December 31, 2008, the Company had approximately $17,000 in borrowings outstanding under the Loan Agreement subject to an interest rate of 9.18%. The Company repaid all borrowings during 2009.

13. 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 will specify 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 year ending December 31, 2009. 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 intends 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. As of December 31, 2009, the Company had approximately $4.0 million in outstanding borrowings under the Agreement.

The Company leases office space and equipment under various operating lease agreements. Rent expense for office space under operating leases amounted to $5.4 million, $5.0 million and $4.9 million for the years ended December 31, 2009, 2008 and 2007, respectively.

In September 2004, the Company entered into an agreement to lease 53,323 square feet of office and laboratory space located at 675 West Kendall Street, Cambridge, Massachusetts, for a term of 80 months (the "West Kendall Sublease"). The Company has an option 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. In November 2005, the Company amended the West Kendall Sublease to lease an additional 25,131 square feet in its current premises 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. The construction period was completed in June 2006. The Company was the owner of the leasehold assets during the construction period, and as of December 31, 2009, the Company has recorded $3.2 million in leasehold improvements offset by $1.0 million as a related lease financing liability.

In October 2006, the Company entered into an agreement to lease approximately 22,300 square feet of office and research space located in Cambridge, Massachusetts (the "Third Street Sublease"). In July 2007, as a result of an evaluation of its space needs, the Company determined that the office and laboratory space leased, but not yet occupied, under the Third Street Sublease was in excess of the Company's present requirements. Accordingly, in October 2007, the Company executed an agreement pursuant to which a third party agreed to assume the Company's rights and obligations under the Third Street Sublease. Under the agreement the third party paid the Company approximately $4.4 million to offset certain rent payments and fees paid by the Company to architects, contractors, brokers and other vendors engaged to build out the space. The effect of this transaction was a reduction in the Company's property and equipment of approximately $3.7 million and a recovery of operating expenses of approximately $0.7 million. In addition, upon the cancellation of the letter of credit associated with the Third Street Sublease, $2.9 million was reclassified from restricted cash to cash and cash equivalents.

Future minimum capital and total operating lease commitments as of December 31, 2009 are as follows (in thousands):

	Operating Lease	Capital Lease
2010	$3,650	$ 2,626
2011	1,280	1,817
2012	—	—
2013	—	—
2014 and beyond	—	—
Total future minimum lease payments	$4,930	4,443
Less—Amounts representing interest		(370)
Capital lease obligation at December 31, 2008		4,073
Less—Current maturities		(2,344)
Capital lease obligation, net of current maturities		$ 1,729

License Agreements

In connection with license arrangements with the research university discussed in Note 8, the Company has certain annual fixed obligations to pay fees for the technology licensed. Beginning in 2010, the annual financial obligations, which extend indefinitely, 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 July 2008, the FDA accepted for review the ANDA containing a paragraph IV certification for generic Copaxone submitted by Sandoz. Subsequently, in August 2008 Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and the Company for patent infringement. In December 2009, in a separate action in the same court, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and the Company for patent infringement related to additional patents after Teva's motion to add those additional patents to the ongoing Paragraph IV litigation was denied. While it is not possible to determine with any degree of certainty the ultimate outcome of the legal proceeding, the Company believes that it has meritorious defenses with respect to the claims asserted against it and intends to vigorously defend its position. In addition, under the terms of the 2006 Sandoz Collaboration, Sandoz AG agreed to indemnify the Company for various claims, including patent infringement claims based on the Company's activities related to partnered programs. The Company has not recorded any accrual for such matter as it is not probable that a loss has been incurred nor is a loss estimable.

14. 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 $0.4 million, $0.3 million and $0.4 million of such match expense in the years ended December 31, 2009, 2008 and 2007, respectively.

15. Related Party Transactions

Parivid, LLC, or Parivid, a company that provided data integration and analysis services to the Company, was considered to be a related party as a co-founder and member of the Company's Board of Directors is the brother of the former chief technology officer of Parivid. In 2007, the Company entered into an Asset Purchase Agreement (the "Purchase Agreement") with Parivid. In connection with 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, for $2.5 million in cash paid at closing and up to $11.0 million in additional payments, which, if certain milestones were achieved, would be paid in a combination of cash and/or stock. 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 December 31, 2008 and 2007.

On August 4, 2009, the Company entered into an Amendment to the Purchase Agreement. Pursuant to the Amendment, 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 in 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.

Additionally, in 2007, the Company recorded an acquired in-process research and development charge of $0.7 million, which is included in research and development expense in the consolidated statement of operations for the year ended December 31, 2007. The Company recorded $0.2 million as research and development expense related to work performed by Parivid in the year ended December 31, 2007.

16. Selected Quarterly Financial Data (Unaudited)

	Quarter Ended			
(in thousands, except per share data)	March 31	June 30	September 30	December 31
2009				
Collaboration revenues	$ 3,990	$ 6,605	$ 4,008	$ 5,646
Net loss	$(17,905)	$(16,772)	$(14,646)	$(14,689)
Basic and diluted net loss per common share	$ (0.46)	$ (0.43)	$ (0.38)	$ (0.34)
Shares used in computing basic and diluted net loss per share	38,744	38,804	39,014	43,615
2008				
Collaboration revenues	$ 4,152	$ 3,563	$ 3,914	$ 2,941
Net loss	$(13,338)	$(14,970)	$(15,959)	$(18,370)
Basic and diluted net loss per common share	$ (0.37)	$ (0.42)	$ (0.45)	$ (0.50)
Shares used in computing basic and diluted net loss per share	35,740	35,773	35,849	36,476

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

Diluted and basic net loss per common share is identical since common equivalent shares are excluded from the calculation, as their effect is anti-dilutive.

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, 2009. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC's 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, 2009, 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

The management of Momenta 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.

Momenta's management, including the supervision and participation of the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2009. In making this assessment, the Company's 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, management has concluded that, as of December 31, 2009, the Company's internal control over financial reporting is effective based on those criteria.

The independent registered public accounting firm that audited the Company's financial statement included in this Annual Report on Form 10-K has issued its report on the effectiveness of the Company's 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, 2009, 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, 2009, 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, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended December 31, 2009 of Momenta Pharmaceuticals, Inc. and our report dated March 12, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 12, 2010

(c) Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended as of December 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2010 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 discussion 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 2010 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 discussion under the heading "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in our definitive proxy statement for the 2010 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 2010 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 2010 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 2010 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. Financial Statements:

2. All schedules are omitted as the information required is either inapplicable or is presented in the financial statements and/or the related notes.

3. The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as a part of this Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized this 12th day of March, 2010.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ CRAIG A. WHEELER
Craig A. Wheeler
Chief Executive Officer

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

Signature	Title	Date
/s/ CRAIG A. WHEELER Craig A. Wheeler	President and Chief Executive Officer; Director (Principal Executive Officer)	March 12, 2010
/s/ RICHARD P. SHEA Richard P. Shea	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2010
/s/ JAMES SULAT James Sulat	Chairman of the Board and Director	March 12, 2010
/s/ JOHN K. CLARKE John K. Clarke	Director	March 12, 2010
/s/ ALAN L. CRANE Alan L. Crane	Director	March 12, 2010
/s/ MARSHA H. FANUCCI Marsha H. Fanucci	Director	March 12, 2010
/s/ PETER BARTON HUTT Peter Barton Hutt	Director	March 12, 2010
/s/ BRUCE DOWNEY Bruce Downey	Director	March 12, 2010
/s/ RAM SASISEKHARAN Ram Sasisekharan	Director	March 12, 2010
/s/ BENNETT M. SHAPIRO Bennett M. Shapiro	Director	March 12, 2010
/s/ ELIZABETH STONER Elizabeth Stoner	Director	March 12, 2010

EXHIBIT INDEX

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
	Articles of Incorporation and By-Laws				
3.1	Third Amended and Restated Certificate of Incorporation	S-1	3.3	3/11/2004	333-113522
3.2	Certificate of Designations of Series A Junior Participating Preferred Stock of the Registrant	8-K	3.1	11/8/2005	000-50797
3.3	Second Amended and Restated By-Laws	S-1	3.4	3/11/2004	333-113522
	Instruments Defining the Rights of Security Holders				
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	4.1	6/15/2004	333-113522
4.2	Investor Rights Agreement, dated as of July 25, 2006, by and between Novartis Pharma AG and the Registrant	10-Q	10.2	11/8/2006	000-50797
	Material Contracts—License Agreements				
10.1†	Collaboration and License Agreement, dated November 1, 2003, by and among Biochemie West Indies, N.V., Geneva Pharmaceuticals, Inc. and the Registrant	S-1/A	10.4	5/11/2004	333-113522
10.2†	Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant (the "November 1, 2002 M.I.T. License"); First Amendment to the November 1, 2002 M.I.T. License, dated November 15, 2002, by and between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated September 12, 2003, between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated October 22, 2003, between the Massachusetts Institute of Technology and the Registrant; Second Amendment to the November 1, 2002 M.I.T. License, dated November 19, 2003, by and between the Massachusetts Institute of Technology and the Registrant; Third Amendment to the November 1, 2002 M.I.T. License, dated April 2, 2004, by and between the Massachusetts Institute of Technology and the Registrant	8-K	10.1	8/15/2006	000-50797

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	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	Incorporated by Reference to			
		Form or Schedule	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				
	Material Contracts—Management Contracts and Compensation Plans				
10.19#	Amended and Restated 2002 Stock Incentive Plan	10-K	10.17	3/15/2007	000-50797
10.20#	2004 Stock Incentive Plan, as amended	10-K	10.18	3/15/2007	000-50797
10.21#	Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.1	8/16/2004	000-50797
10.22#	Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.2	8/16/2004	000-50797
10.23#	Form of Restricted Stock Agreement under 2004 Stock Incentive Plan	8-K	10.2	2/28/08	000-50797
10.24#	2004 Employee Stock Purchase Plan	S-1/A	10.3	4/16/2004	333-113522
*10.25#	Non-Employee Director Compensation Summary				
10.26#	Restricted Stock Agreement, dated March 7, 2006, between Ganesh Venkataraman and the Registrant	10-Q	10.14	11/8/2006	000-50797
10.27#	Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.28#	Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.8	11/8/2006	000-50797
10.29#	Nonstatutory Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.9	11/8/2006	000-50797

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.30#	Incentive Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.10	11/8/2006	000-50797
10.31#	Restricted Stock Agreement, dated March 7, 2006, between Steven B. Brugger and the Registrant	10-Q	10.13	11/8/2006	000-50797
10.32#	Restricted Stock Agreement, dated December 15, 2006, between John E. Bishop and the Registrant	10-K	10.56	3/15/2007	000-50797
10.33#	Restricted Stock Agreement, dated December 14, 2007, between John E. Bishop and the Registrant	10-K	10.35	3/10/2008	000-50797
10.34#	Restricted Stock Agreement, dated August 15, 2007, between Richard P. Shea and the Registrant	10-Q	10.1	11/08/2007	000-50797
10.35#	Restricted Stock Agreement, dated January 17, 2007, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.36#	Form of Employment Agreement for executive officers	10-Q	10.3	5/9/2008	000-50797
10.37#	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
10.38#	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
10.39#	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
10.40#	Amendment No. 1 to the Restricted Stock Agreement made on March 7, 2006 between the Registrant and Steven Brugger dated November 4, 2009.	10-Q	10.1	11/5/2009	000-50797
*10.41#	Amendment No. 1 to the Restricted Stock Agreement made on March 7, 2006 between the Registrant and Ganesh Venkataraman dated November 4, 2009.				
	Material Contracts—Credit Agreements				
10.42	Loan and Security Agreement, dated December 27, 2002, by and between Silicon Valley Bank and the Registrant	S-1	10.23	3/11/2004	333-113522
10.43	First Loan Modification Agreement, dated December 28, 2004, between Silicon Valley Bank and the Registrant	10-K	10.37	3/31/2005	000-50797

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to Exhibit No.	Filing Date with SEC	SEC File Number
10.44	Loan and Security Agreement, dated December 28, 2004, between Silicon Valley Bank and the Registrant	10-K	10.38	3/31/2005	000-50797
10.45	Master Lease Agreement, dated December 30, 2005, between General Electric Capital Corporation and the Registrant	10-K	10.44	3/16/2006	000-50797
	Material Contracts—Leases				
10.46†	Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.9	11/12/2004	000-50797
10.47	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
10.48	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
10.49	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
10.50	Letter Agreement (regarding Sublease Agreement, dated September 14, 2004, as amended), dated June 29, 2006, between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.01	8/9/2006	000-50797
	Material Contracts—Stock Purchase Agreement				
10.51	Stock Purchase Agreement, dated July 25, 2006, by and between Novartis Pharma AG and the Registrant	10-Q	10.1	11/8/2006	000-50797
	Material Contracts—Asset Purchase Agreement				
10.52	Asset Purchase Agreement dated as of April 20, 2007 by and among Parivid, LLC, S. Raguram and the Registrant	10-Q	10.3	5/10/2007	000-50797
10.53	Amendment No.1 to the April 20, 2007Asset 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
	Additional Exhibits				
*21	List of Subsidiaries				
*23.1	Consent of Independent Registered Public Accounting Firm				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				

* Filed herewith.

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

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

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