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, 2008

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 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, 2008, based on $12.30 per share, the last reported sale price of Common Stock on the Nasdaq Global Market on that date, was $300,783,708.

As of February 27, 2009, the registrant had 39,884,814 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 2009 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 with a product pipeline of both complex mixture generic and novel drugs. This pipeline is derived from our proprietary, innovative technology platform for the detailed structural analysis of complex mixture drugs. We use this platform to study the *structure* (thorough characterization of chemical components), *structure-process* (design and control of manufacturing process), and *structure-activity* (relating structure to biological and clinical activity) of complex mixture drugs. The development product candidates and research programs from our generic and novel product candidate portfolios are outlined below.

Momenta Pharmaceuticals—Product and R&D Pipeline

	Generic Drugs and Follow-on Biologics (FOBs)	Novel Drugs
Development Product Candidates	M-Enoxaparin (Generic Lovenox®) M356 (Generic Copaxone®) M178 (FOB)	M118 (Anticoagulant)
Research Programs	Glycoproteins (FOB)	Oncology

Complex Generic and Follow-on Biologics Product Portfolio

Our complex mixture generics and follow-on biologics effort is focused on building a thorough understanding of the *structure-process-activity* of complex mixture 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 a 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 design and control our manufacturing process to manufacture reproducibly 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 generic or follow-on versions of complex mixture products, thereby providing high quality, safe and affordable medicines to patients in need.

Our two most advanced complex generic 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 regulatory pathway for generic product candidates and submit an Abbreviated New Drug Application, or ANDA, for these generic candidates. ***M-Enoxaparin*** is designed to be a technology-enabled 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. This drug is a complex mixture of polysaccharide chains derived from naturally sourced heparin. Our second major generic product candidate is ***M356***, a technology-enabled generic version of Copaxone® (glatiramer acetate injection), a drug that is indicated for the reduction of the frequency of relapses in patients with Relapse-Remitting Multiple Sclerosis, or RRMS. Copaxone consists of a complex mixture of polypeptide chains. With M356, we have extended

our core characterization capabilities from the characterization of complex polysaccharide mixtures to include the characterization of complex polypeptide mixtures.

In addition to our two complex generic product candidates, which are both currently under review by FDA, we have further extended our analytical and development platform to pursue generic or follow-on versions of biologic drugs. Our efforts on ***M178***, as well as our ongoing ***Glycoprotein Research Program***, are focused on developing generic or follow-on versions of marketed therapeutic proteins which are derived from natural or cell based manufacturing processes. By thoroughly characterizing these biologic molecules, we seek to gain a deeper understanding of the relationship between their manufacturing processes and final product compositions. Our goal is to replicate our development approach with M-Enoxaparin and M356 and pursue the development and commercialization of multiple generic or follow-on versions of marketed therapeutic proteins.

Novel Drugs Portfolio

Our complex mixture novel drug research and development efforts leverage our analytical technology platform and *structure-process* knowledge to develop novel drugs by studying the *structure-activity* of complex mixtures and develop novel drugs. With our capabilities to thoroughly characterize complex mixtures, we are targeting our efforts to understand the relationship between structure and the biological and therapeutic activity of various complex mixture drugs. Our goal is to capitalize on the structural diversity and multi-targeting potential of these complex mixtures to engineer novel drugs that we believe will meet key unmet medical needs in various diseases. While we believe that our capabilities to engineer improved and novel complex mixture drugs can be applied across several product categories with significant therapeutic potential, such as polysaccharides, polypeptides and glycoproteins, our initial focus has been in the area of complex polysaccharide mixtures.

Our lead novel 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. We also are seeking to discover and develop novel therapeutics by applying our technology to better understand the function of these polysaccharide mixtures in biological processes, with an initial focus in oncology.

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" 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 for the study of complex mixtures utilizes three different types of analytical tools. First, we have accumulated a comprehensive library of enzymes that we use to break down the components of a complex mixture into smaller, 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 components, structure and arrangement of the chemical building blocks of the complex mixture. Third, we apply proprietary mathematical methods to describe the complete composition of each complex mixture product candidate. It is the combination of these tools that enables us to characterize complex polysaccharide, polypeptide and protein mixtures.

While a similar integrated analytical approach is applied across different product categories, we develop a unique characterization toolkit for each specific complex mixture product candidate. Once the chemical components of the complex mixture are known (*structure*), we (1) further employ these methods and data sets in the design and control of our manufacturing process (*structure-process*) to produce generic and FOB versions of marketed drugs, and (2) relate structure to biological and clinical activity (*structure-activity*) to support our complex generic product candidates. We use a similar approach to engineer novel drugs to meet key unmet medical needs in various diseases.

Product Candidates

M-Enoxaparin

Our most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox. 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 sugar chains that, in our view, prior to the application of our technology, had not been adequately analyzed. The length and sequence of the sugar 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 a New Drug Application, or 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). 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 mixtures 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 three other follow-on and complex generic 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 $4.0 billion in 2008, with approximately $2.4 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. Both ANDAs currently include a Paragraph IV certification stating that Sanofi-Aventis' patents for Lovenox listed in the Orange Book, which lists all approved drug products and therapeutic equivalence evaluations, are, among other things, invalid and unenforceable. The FDA is currently reviewing the M-Enoxaparin ANDAs, including our manufacturing data and technology and characterization methodology. In November 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin was not approvable in its then-current form because the ANDA did not adequately address the potential for immunogenicity of the drug product. Starting in early 2008, we and Sandoz conferred with the FDA concerning the design of studies to address the FDA's concerns in this area. These interactions led to the FDA's general concurrence with our proposed approach and to the submission of an immunogenicity amendment to the M-Enoxaparin ANDA in September 2008. Although the ANDA review process is ongoing, the FDA has not requested human clinical trials at this time. However, there can be no assurances that the FDA will not require such 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 working together to prepare for the commercialization of M-Enoxaparin, if and when approved, by advancing manufacturing, supply chain, and sales and marketing objectives.

Under the Hatch-Waxman Act, the first applicant to submit an ANDA for review by the FDA that includes a Paragraph IV certification may be eligible to receive a 180-day period of generic market exclusivity. Both Amphastar Pharmaceuticals, Inc., or Amphastar, and Teva Pharmaceuticals USA, Inc., or Teva, submitted ANDAs containing Paragraph IV certifications prior to Sandoz' submission of the ANDA for M-Enoxaparin, and either (or both) companies may have rights to a 180-day market exclusivity period. The Teva and Amphastar ANDAs were filed prior to December 8, 2003; consequently, the outcome of litigation between Sanofi-Aventis and Teva and Amphastar resulted in the triggering of the 180-day exclusivity period in early October 2008, without any company receiving final ANDA approval. Sandoz must wait until the expiration of this 180-day period, or April 1, 2009, before being eligible to receive final FDA approval for its ANDA. Although neither Amphastar nor Teva has received an ANDA approval as of March 1, 2009, either or both companies may obtain approval before Sandoz and may establish long term supply agreements with institutional customers before Sandoz can enter the market, which would hinder Sandoz' ability to penetrate the market for generic enoxaparin products.

Legal Matters

Amphastar/Teva Patent Infringement Lawsuit

In September 2003, Amphastar and Teva each separately filed an ANDA for enoxaparin containing a Paragraph IV certification. In response, Sanofi-Aventis brought lawsuits for patent infringement against both companies. A decision of the Court of Appeals for the Federal Circuit, or Court of Appeals, in May 2008 affirmed a district court decision holding Aventis's Orange Book patents on Lovenox unenforceable due to inequitable conduct. In September 2008, the Court of Appeals denied Sanofi-Aventis' petition for a rehearing or rehearing en banc. In January 2009, Sanofi-Aventis petitioned the United States Supreme Court for review of the case. The ability to commercialize and market M-Enoxaparin may depend, in part, upon the final outcome of this litigation and we cannot be certain when the outcome of the litigation will be final.

Sandoz Patent Infringement Lawsuit

In response to the Paragraph IV certifications contained in the Sandoz ANDAs for M-Enoxaparin, Sanofi-Aventis brought patent infringement suits against Sandoz. Sandoz moved to dismiss the suits based upon the decision in the Amphastar/Teva case, and in September 2008, the District Court ruled in favor of Sandoz. Sanofi-Aventis has appealed this decision to the Court of Appeals and this appeal is pending. The automatic 30-month stay that issued upon the initiation of this case, which prohibited FDA approval of Sandoz' ANDA, terminated in August 2008 upon the entry of the final judgment in the District Court. However, if this case is not dismissed on appeal, or a dismissal is reversed on a further petition to the Supreme Court, the ability to commercialize and market M-Enoxaparin could be significantly affected. We cannot be certain when the outcome of this case will be final or provide assurance that we will ultimately prevail.

Neither Teva nor Amphastar are currently marketing a generic version of enoxaparin in the United States, nor can they market such a product in the United States unless the FDA approves Amphastar's or Teva's respective ANDA filings.

M356

M356 is designed to be a generic version of Copaxone (glatiramer acetate injection), a drug consisting of a complex mixture of polypeptide chains. Copaxone is indicated for the 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. Copaxone and several interferon beta products are among the leading products marketed for treating multiple sclerosis.

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 $2.3 billion in 2008, with approximately $1.4 billion from the U.S. market.

Regulatory Matters

In December 2007, Sandoz submitted an ANDA in its name to the FDA 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' ANDA eligible for the grant of a 180-day generic exclusivity period upon approval.

Legal Matters

Teva has listed seven patents in the Orange Book for Copaxone, all of which expire in May 2014. In August 2008, in response to Sandoz' ANDA filing and the Paragraph IV certification, Teva Pharmaceutical Industries Ltd. and related entities sued Sandoz, Novartis AG and us for patent infringement. Upon initiation of this litigation, an automatic 30-month stay issues precluding the approval of the ANDA filed by Sandoz. 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.

M118

M118 is a novel anticoagulant that 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.

Description of Our Program

M118 was rationally designed utilizing our proprietary analytical methods and technology to address multiple desirable clinical attributes of anticoagulation therapy for ACS in a single agent. These attributes 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. The results of our preclinical animal studies 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.
- *Reversibility.* Animal results also suggest 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, we believe 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. These assays, which include activated clotting time, or ACT, are routinely used during interventional procedures. Currently, existing marketed LMWHs cannot be monitored efficiently with such routine laboratory tests.

Based on analysis of Phase 1 clinical data, M118 has shown anticoagulant activity in a dose-dependent manner that is reversible with protamine sulfate and is monitorable with a rapid point-of-care assay, or ACT. The Phase 1 clinical data also indicate that M118 can be concomitantly administered with other agents typically utilized to treat ACS, including aspirin, thienopyridines, and glycoprotein IIb/IIIa inhibitors. We expect that the ongoing Phase 2 clinical study will provide important information about the ability to use M118 as a procedural anticoagulant. Additional Phase 2 clinical studies are being planned to explore the use of M118 in patients diagnosed with ACS who are either managed medically or proceed to early intervention via percutaneous coronary intervention, or PCI.

Potential Commercial Market

The broad anticoagulant/antithrombotic market is projected to generate greater than $6 billion in worldwide sales in 2010. 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 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 October 2007, we began 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. We expect enrollment in the Phase 2a clinical trial to conclude in the second quarter of 2009.

In March 2007, we filed 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.

We are not currently able to estimate the timing of regulatory approval of M118.

Glycoproteins

We are applying our technology to the development of either generic or biosimilar glycoprotein products. We believe that this technology can further be used in assisting pharmaceutical and biotechnology companies in developing improved and next-generation versions of their branded products by analyzing and modifying the protein mixture, and can also be used to engineer novel complex mixture drugs.

Description of Our Program

Our glycoprotein program is focused on extending our technology for the analysis of complex sugars to glycoproteins. The goal of the program is to facilitate the development of follow-on biologics, or biogeneric or biosimilar versions of major marketed glycoprotein products. Under our 2006 Sandoz Collaboration, we are currently applying our technology to develop a generic or follow-on version of a marketed glycoprotein in partnership with Sandoz. We refer to this product candidate as M178.

Potential Commercial Market

Therapeutic proteins represent a sizable segment of the U.S. drug industry, with sales expected to exceed $60 billion by 2010. Most of these products are glycoprotein drugs, which 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. Given the inadequacies of standard technology, many of these glycoproteins have not been thoroughly characterized.

Regulatory Matters

Many glycoprotein drugs are complex mixture drugs that have been approved by the FDA under the Biologic 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 EU. 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 U.S. regulatory pathway in the future.

Discovery Program

Our discovery program is focused on the role that complex sugars play in biological systems, including regulating the development and progression of disease. Our initial focus is in the area of cancer, a disease characterized by unregulated cell growth, where we are seeking to discover sugar sequences with anti-cancer properties for development as therapeutics. We are evaluating an oncology product candidate that is in the advanced discovery phase. Sugars play a part in the conversion of normal cells into cancerous cells, the regulation of tumor growth and tumor invasion and metastasis. We believe that our technology can provide us with a better understanding of the role of sugars in disease, enabling us to discover novel sugar therapeutics, as well as to discover new disease mechanisms that can be targeted with other small molecule and biologic drugs.

Research and Development Expenses

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, contract research and manufacturing, and the costs of laboratory equipment and facilities. Research and development expense for 2008 was $55.3 million, compared with $69.9 million in 2007 and $46.9 million in 2006.

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 agreement, provide to us a share of the profits from M-Enoxaparin. Alternatively, if there are one or more third party competitors marketing a Lovenox-Equivalent Product, Sandoz will either pay a royalty to us based on net sales of M-Enoxaparin or pay a combination of royalty payments and a share of profits, depending on certain circumstances. 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, the royalties and the 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, the royalties and the 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' profit sharing, royalty and milestone payment obligations survive and Sandoz' obligation to indemnify us will survive with respect to claims that arise due to Sandoz' 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 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 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, we and Sandoz AG terminated the collaborative program with regard to one of the follow-on products, M249, primarily due to its commercial prospects.

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. 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 which approves the annual collaboration plan. Sandoz AG is responsible for commercialization activities and will exclusively distribute and market the products.

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, we are 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 us and Sandoz AG. We are also paid for full-time equivalent employees performing development services where development activities are funded solely by Sandoz AG, or partly by proportion where development costs are shared between us and Sandoz AG. The parties will share profits in varying proportions, depending on the product. We are eligible to receive up to $178.0 million in milestone payments if all milestones are achieved for the three 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.

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, the following termination rights apply to some of the products, on a product-by-product basis:

- if clinical trials are required;
- if the parties agree, or the relevant regulatory authority states in writing, that our intellectual property does not contribute to product approval;
- if Sandoz decides to permanently cease development and commercialization of a product; or
- by either party with respect to certain products if, following a change of control of the other party, such other party fails to perform its material obligation with respect to such product.

In addition, through the period ending July 24, 2011, we and Sandoz may negotiate additional collaboration agreements with respect to certain products, including expanded territories for certain products already part of the collaboration. If we and Sandoz do not execute a definitive agreement within a specified time frame, we are permitted to enter into a transaction for such opportunity with a third party, provided that the terms which we give to that third party can be no less favorable, taken as a whole, to us than the terms last offered to Sandoz. If we do not enter into a transaction with a third party in a specified time frame, then the negotiations between us and Sandoz with respect to such product will start again, with the corresponding rights and obligations if the parties do not execute a definitive agreement within the specified time frame.

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 sugars 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 sugars;
- 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 commencing in 2005 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 $157,500. We are also required to pay M.I.T. royalties on certain products and services covered by the licenses and sold by us or our affiliates or sublicensees, a percentage of certain other income received by us from corporate partners and sublicensees, and certain patent prosecution and maintenance costs. We recorded $107,500, $82,500 and $487,500 as expenses related to these agreements in the years ended December 31, 2008, 2007 and 2006, 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 31 United States patents that expire between 2012 and 2023 and foreign counterparts of some of these. 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 69 patent families, which presently includes 32 United States patents and 68 United States patent applications 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 sugars and other heterogeneous mixtures;
- the use of certain naturally occurring heparinases, heparinase variants and other enzymes;
- methods and technologies for synthesis of sugars;
- the composition of matter of certain novel LMWHs, including M118;
- methods to identify and analyze sugars associated with glycoproteins;
- methods of manufacture of certain polysaccharide, polypeptide and glycoprotein products;
- methods to analyze and monitor glycoprotein profiles for purposes associated with the diagnosis, staging, prognosis and monitoring of cancer; and
- methods for the *in vivo* non-invasive delivery of sugars.

A significant portion of our patent portfolio covering methods and technologies for characterizing sugars 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, the methods and technologies for chemical synthesis of sugars, and the composition of matter of novel low molecular weight heparins 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 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, payable in a combination of cash and/or stock, if certain milestones are achieved.

The contingent milestone payments include potential cash payments of no more than $2.0 million if certain milestones are achieved within two years from the date of the Purchase Agreement and 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. We believe that it is likely that we will make substantially all or all of the $2.0 million cash payment in 2009. In addition, upon the completion and satisfaction of those milestones that trigger the issuance of shares of our common stock, we granted Parivid certain registration rights under the Securities Act of 1933, as amended, with respect to such shares. We also entered into an employment agreement with S. Raguram pursuant to the terms of the Purchase Agreement.

As part of our acquisition of assets from Parivid, two previous collaboration agreements we had in place with Parivid were terminated. S. Raguram is the brother of Ram Sasisekharan, a member of our Board of Directors. Ram Sasisekharan received no consideration in connection with the execution of the Purchase Agreement. We recorded $0.2 million and $1.0 million as research and development expense related to work performed by Parivid in the years ended December 31, 2007 and 2006, respectively.

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 both 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. In the event that we were to 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 will 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 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 AVE5026 and idrabiotaparinux ,which are being developed by Sanofi-Aventis, rivaroxaban, which is being developed by Bayer AG and Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and apixiban, 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.

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. In addition, GlaxoSmithKline's Arixtra, which is approved in DVT, 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 mixtures, there are several competitors seeking to provide additional characterization or create biosimilar, generic, and/or improved versions of marketed complex products. GlycoFi, a wholly-owned subsidiary of Merck & Co., Inc., possesses selected analytical and engineering capabilities which could be applied to creating biosimilar, generic, or improved versions of complex protein-based products. Companies such as Teva, Sandoz, BioGenerix AG, Stada Arzneimittel, Cangene Corporation and GeneMedix Ltd., a wholly-owned subsidiary of Reliance Life Sciences, also have disclosed intentions to develop and commercialize generic and/or improved versions of marketed protein products in the U.S. or Europe. Most of these companies have experience with manufacturing complex protein products or with commercializing generic 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. One company competing most directly with our approach of developing sugar-based therapeutics for oncology is Progen Industries Limited. Pfizer Health AB has also conducted investigative clinical trials using Fragmin as a therapeutic drug for cancer; while there are no approved indications, selected trials are ongoing.

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 sugars as therapeutics, companies focused on engineering or modifying sugars, 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 sugars. 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 Neose Technologies, 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 follow either the NDA or BLA routes, 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 generic or follow-on biologic under the Public Health Service Act.

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 current 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 product for each 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 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; 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 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. 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. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA 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.

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. 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.

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. 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

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.

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 glycoprotein 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. 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 conditions of their 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.

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 exclusivity periods, 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 uses or versions of previously approved drugs, 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 extension.

Post-Approval Requirements

After regulatory approval of a product is obtained, we are 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 monitor the product's safety or efficacy. Our 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 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 certain 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 a clinical hold on or termination of studies, the FDA's refusal to approve pending applications, 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.

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, unenforceable and/or not 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 law, as amended by the Medicare Modernization Act of 2003, or MMA, there are a number of ways an applicant who has filed an ANDA after the date of the MMA may forfeit its 180-day exclusivity, including if the ANDA is withdrawn or if the applicant fails to market its product within the specified statutory timeframe or achieve at least tentative approval within the specified timeframe. In addition, for ANDAs filed after the MMA was enacted, it is possible for more than one ANDA applicant to be eligible for 180-day exclusivity. This occurs when multiple "first" applicants submit substantially complete ANDAs with paragraph IV certifications on the same day.

Follow-on Biologics

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 EU. Pending 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 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 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. Under this procedure, the holder of a national marketing authorization from one EU 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 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, 2008, we had 167 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.

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, 2008, our accumulated deficit was $257.0 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. In November 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin was not approvable because the ANDA did not adequately address the potential for immunogenicity of the drug product. In September 2008, Sandoz submitted an amendment to the M-Enoxaparin ANDA. 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 the response filed in September 2008 fails to answer the FDA's questions related to the potential for immunogenicity of the drug product;
- if we fail to answer any subsequent questions from the FDA to its satisfaction as it proceeds with its review of the M-Enoxaparin ANDA;
- 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 the ANDA (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. filed 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 marketing of M-Enoxaparin would be materially adversely affected. 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. Under the Hatch-Waxman Act, any developer of a generic drug that is first to have its ANDA accepted for review by the FDA, and whose submission includes a paragraph IV certification, is eligible to receive a 180-day period of generic market exclusivity. Sandoz was not the first applicant to file an enoxaparin ANDA with a paragraph IV certification, so Sandoz will be forced to wait until the expiration of Teva and/or Amphastar's exclusivity period, which will be April 1, 2009, before being able to receive FDA final approval of its application. As a result, Teva and/or Amphastar may have the opportunity to establish long term supply agreements with institutional customers before we can enter the market, which would hinder our ability to penetrate the market for generic enoxaparin products.

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.

Our patent litigation with Teva Pharmaceutical Industries Ltd., the innovator 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. This litigation 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 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. 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.

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, require independent third-party analysis or 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 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 recommneded that manufacturers and suppliers of UFH use additional tests to screen their UFH active pharmaceutical

ingredient. The FDA has 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 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, experience manufacturing difficulties or are unable to manufacture sufficient quantities of our product candidates, including M-Enoxaparin and M118, 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, 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 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, 2008, we had cash, cash equivalents and marketable securities totaling $108.5 million. For the year ended December 31, 2008, we had a net loss of $62.6 million and used cash in operating activities of $48.2 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 potential patent litigation with Sanofi-Aventis relating to Lovenox or with Teva Pharmaceuticals Industries relating to Copaxone that, in either case, 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 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.

Patent litigation with Sanofi-Aventis, the innovator of Lovenox, may cause delays and additional expense in the commercialization of M-Enoxaparin. If we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, our business would be materially harmed, which could include, without limitation, the curtailment of our other development programs.

Amphastar/Teva Patent Infringement Lawsuit

In September 2003, Amphastar and Teva each separately filed an ANDA for enoxaparin containing Paragraph IV certifications. In response, Sanofi-Aventis brought lawsuits for patent infringement against both companies. A decision of the Court of Appeals for the Federal Circuit, or Court of Appeals, in May 2008 affirmed a district court decision holding Aventis' patent on Lovenox unenforceable due to inequitable conduct. In September 2008, the Court of Appeals denied Sanofi-Aventis' petition for a rehearing or rehearing en banc. In January 2009, Sanofi-Aventis petitioned the United States Supreme Court for review of the case. The ability to commercialize and market M-Enoxaparin, may depend in part upon the final outcome of this litigation and we cannot be certain when the outcome of the litigation will be final.

Sandoz Patent Infringement Lawsuit

In response to the Paragraph IV certifications contained in the Sandoz ANDAs for M-Enoxaparin, Sanofi-Aventis brought patent infringement suits against Sandoz. Sandoz moved to dismiss the suits based upon the decision in the Amphastar/Teva case, and in September 2008 the District Court ruled in favor of Sandoz. Sanofi-Aventis has appealed this decision to the Court of Appeals and this appeal is pending. The automatic 30-month stay, which issued upon the initiation of this case and prohibited FDA approval of Sandoz' ANDA, terminated in August 2008 upon the entry of the final judgment in the District Court. However, if this case is not dismissed on appeal, or a dismissal is reversed on a further petition to the Supreme Court, the ability to commercialize and market M-Enoxaparin could be significantly affected. We cannot be certain when the outcome of this case will be final or provide assurance that we will ultimately prevail.

Under our 2003 Sandoz Collaboration, the decision as to when to begin marketing M-Enoxaparin if the ANDA is approved will be determined jointly by us and Sandoz in most circumstances. However, Sandoz does have sole discretion over the decision as to when to begin marketing M-Enoxaparin under certain circumstances. Sandoz could decide to market M-Enoxaparin "at risk," that is prior to final

resolution of either the Teva and Amphastar or Sandoz litigation matters, which could result in significant damages, including possibly treble damages, in the event Sanofi-Aventis is successful in either patent litigation case. Although Sandoz has agreed to indemnify us for patent liability damages, Sandoz has the right to offset certain of these liabilities against the profit-sharing amounts, the royalties and the milestone payments otherwise due to us from the marketing of M-Enoxaparin.

Litigation involves many risks and uncertainties, and there is no assurance that Amphastar, Teva, Sandoz or we will prevail in any lawsuit with Sanofi-Aventis. In addition, Sanofi-Aventis has significant resources and any litigation with Sanofi-Aventis could last a number of years, potentially delaying or prohibiting the commercialization of M-Enoxaparin. If, as a result of protracted litigation, we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, we may have to curtail our other product development programs and our business would be materially harmed.

We will need to develop or acquire additional technologies as part of our efforts to analyze the chemical composition of complex mixture drugs.

In order to adequately analyze other complex mixture drugs, such as glycoproteins, we will need to develop or acquire new technologies. Our inability to develop or acquire and apply these new technologies would impair our ability to develop improved, next-generation or follow-on versions of existing products. Our inability to develop or acquire additional technology for the characterization of complex mixtures could reduce the likelihood of our success developing additional products.

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;
- 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;
- the availability and cost of manufacturing, marketing, distribution and sales capabilities;

- the effectiveness of our marketing, distribution and sales capabilities;
- the price of our products;
- the availability and amount of third-party reimbursement for our products; and
- the strength of our patent position.

Our competitors may develop or commercialize products with significant advantages in regard to any of these factors. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business.

If we 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 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 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 drug candidates, the market may not be receptive to our drug candidates upon their commercial introduction, which could prevent us from being profitable.

Even if our drug candidates are successfully developed, our success and growth will also depend upon the acceptance of these drug candidates by physicians and third-party payors. Acceptance of our product development 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 drug 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;
- 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.

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 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, 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 new licensing requirements for sales representatives and new 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.

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.

If the United States Congress does not take action to create an abbreviated regulatory pathway for follow-on biologics, and if the FDA is not able to establish specific guidelines regarding the scientific analyses required for characterizing follow-on versions of biologics and complex protein drugs, 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 recent legislative activity, 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.

If our preclinical studies and clinical trials for our development candidates, including M118, 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 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;
- 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 or our product candidates beyond those that we currently contemplate, 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 outside of the United States. 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, submitting or 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 drugs 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 drugs and our business would be seriously harmed.

Even after approval, any drug products we develop will be subject to ongoing regulatory review, including the review of clinical results which are reported after our drug products are made commercially available. In addition, the manufacturer and manufacturing facilities we use to produce any of our drug candidates will be subject to periodic review and inspection by the FDA. 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 drug or manufacturer or facility, including withdrawal of the drug 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 continuing FDA regulatory requirements, we may be subject to warning letters, civil penalties, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions 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.

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 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 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.

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;
- 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, we and Sandoz may be unable to obtain approval of our ANDA for M-Enoxaparin, which would materially harm our business.

In September 2008, 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. The FDA has yet to rule on the Citizen Petition, and 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.

Federal legislation will increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any.

The Medicare Prescription Drug Improvement and 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.

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, 2008, 2007 and 2006, we spent approximately $65,000, $64,000 and $31,000, 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. However, we may not hold proprietary rights to some patents related to our current or future product candidates. 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. In addition, the issuance of a patent does not guarantee that we have the right to practice the patented invention. 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.

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.

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 becoming

more 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, the following termination rights apply to some of the products, on a product-by-product basis: if clinical trials are required; if the parties agree, or the relevant regulatory authority states in writing, that our intellectual property does not contribute to product approval; if Sandoz decides to permanently cease development and commercialization of a product; by either party with respect to certain products if, following a change of control of the other party, the other party fails to perform its material obligations with respect to such product. 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 supplement and enhance our own capabilities or fund our development efforts. 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, we may need to enter into alliances or collaborations with other companies that can assist with the development and commercialization of our drug candidates. 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 drug 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 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. 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

Our directors, executive officers and major stockholders have substantial influence or control over matters submitted to stockholders for approval that could delay or prevent a change in corporate control.

Our directors, executive officers and principal stockholders, together with their affiliates and related persons, beneficially owned, in the aggregate, approximately 23.7% of our outstanding common stock as of December 31, 2008. As a result, these stockholders, if acting together, may have the ability to significantly influence matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of

our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;
- entrenching our management and/or board of directors;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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 ANDA;
- other adverse FDA decisions relating to M-Enoxaparin or M356, including an FDA decision to require additional data, including requiring clinical trials, as a condition to M-Enoxaparin or M356 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 Sanofi-Aventis in any of the current patent litigation matters, or a settlement related to any of those cases;
- 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; and
- 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, 2009, 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 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 for M356. The suit alleges infringement of certain patent rights held by Teva and Yeda by us, Sandoz and Novartis AG and seeks monetary, injunctive and declaratory relief. In addition, Teva and Yeda allege 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' 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.

While we intend to vigorously defend this suit and prosecute our counterclaims, and we believe that we can ultimately prove our case in court, litigation involves many risks and uncertainties, and the litigation could last a number of years. As a result, this litigation 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. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

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

Market Information

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

Quarter ended	High	Low
March 31, 2007	$20.13	$11.42
June 30, 2007	16.10	10.08
September 30, 2007	12.02	9.49
December 31, 2007	13.38	4.87
March 31, 2008	12.21	5.97
June 30, 2008	14.94	10.61
September 30, 2008	19.53	12.66
December 31, 2008	13.18	6.99

Holders

On February 27, 2008, the approximate number of holders of record of our common stock was 64.

Dividends

We have never declared or paid any cash dividends on our common stock. We anticipate that, in the foreseeable future, we will continue to retain any earnings for use in the operation of our business and will not pay any cash dividends.

Equity Compensation Plan Information

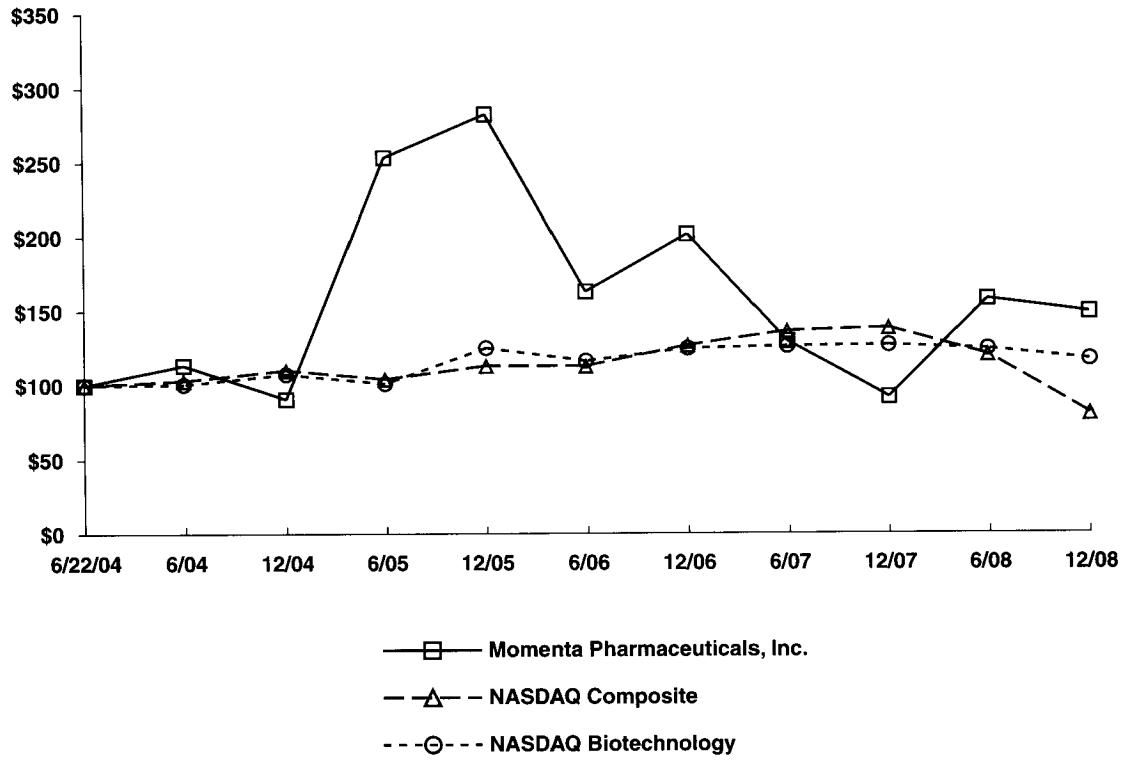
Information relating to compensation plans under which our equity securities are authorized for issuance is set forth in Item 12 below.

Stock Performance Graph

The comparative stock performance graph below compares the cumulative total stockholder return (assuming reinvestment of dividends, if any) from investing $100 on June 22, 2004, the date on which our common stock was first publicly traded, through December 31, 2008, in each of (i) our common stock, (ii) The NASDAQ Composite Index and (iii) The NASDAQ Biotechnology Index (capitalization weighted).

COMPARISON OF 54 MONTH CUMULATIVE TOTAL RETURN*

Among Momenta Pharmaceuticals, Inc., The NASDAQ Composite Index
And The NASDAQ Biotechnology Index



*$100 invested on 6/22/04 in our common stock and $100 invested on 5/31/04 in each of the NASDAQ Composite Index and the NASDAQ Biotechnology Index, including reinvestment of dividends. Fiscal year ending December 31.

	Base Period*	6/30/04	12/31/04	6/30/05	12/31/05	6/30/06	12/31/06	6/30/07	12/31/07	6/30/08	12/31/08
Momenta Pharmaceuticals, Inc. . . .	100.00	113.32	90.40	253.14	282.20	162.74	201.41	129.07	91.42	157.49	148.53
NASDAQ Composite	100.00	103.12	110.04	104.05	112.84	112.64	126.46	135.99	138.08	119.87	80.44
NASDAQ Biotechnology	100.00	100.50	107.25	100.91	124.80	116.04	124.34	125.74	126.43	123.82	116.74

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, 2008, 2007 and 2006 and the balance sheet data as of December 31, 2008 and 2007 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, 2005 and 2004 and the balance sheet data as of December 31, 2006, 2005 and 2004 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,				
	2008	2007	2006	2005	2004
	(In thousands, except per share information)				
Statements of Operations Data:					
Collaboration revenue	$ 14,570	$ 21,561	$ 15,999	$ 13,011	$ 7,832
Operating expenses:					
Research and development	55,301	69,899	46,916	23,710	15,722
General and administrative	24,591	28,219	28,466	14,059	6,751
Total operating expenses	79,892	98,118	75,382	37,769	22,473
Loss from operations	(65,322)	(76,557)	(59,383)	(24,758)	(14,641)
Interest income	3,483	8,484	7,974	3,353	605
Interest expense	(798)	(808)	(504)	(257)	(39)
Net loss	$(62,637)	$(68,881)	$(51,913)	$(21,662)	$(14,075)
Net loss attributable to common stockholders	$(62,637)	$(68,881)	$(51,913)	$(21,662)	$(36,316)
Basic and diluted net loss per share attributable to common stockholders	$ (1.74)	$ (1.93)	$ (1.62)	$ (0.79)	$ (2.56)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	35,960	35,639	32,103	27,283	14,177

	As of December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 55,070	$ 33,038	$ 22,351	$ 25,890	$ 11,678
Marketable securities	53,461	102,899	168,914	130,364	41,943
Working capital	93,483	125,293	185,299	155,661	54,154
Total assets	132,201	168,298	216,385	171,101	64,330
Total long-term obligations	13,604	7,971	7,057	2,996	1,105
Total liabilities	32,696	40,758	33,794	10,946	7,337
Accumulated deficit	(257,037)	(194,400)	(125,519)	(73,606)	(51,944)
Total stockholders' equity	$ 99,505	$ 127,540	$ 182,591	$160,155	$ 56,993

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 with a product pipeline of both complex mixture generic and novel drugs. This pipeline is derived from our proprietary, innovative technology platform for the detailed structural analysis of complex mixture drugs. We use this platform to study the *structure* (thorough characterization of chemical components), *structure-process* (design and control of manufacturing process), and *structure-activity* (relating structure to biological and clinical activity) of complex mixture drugs.

Our complex mixture generics and follow-on biologics effort is focused on building a thorough understanding of the *structure-process-activity* of complex mixture 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 design and control our manufacturing process to reproducibly manufacture an equivalent version of the marketed product. Where necessary, and as required by the 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 generic or follow-on versions of complex mixture products, thereby providing high quality, safe and affordable medicines to patients in need.

Our two most advanced complex generic 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 submit an Abbreviated New Drug Application, or ANDA, for these generic candidates. ***M-Enoxaparin*** is designed to be a technology-enabled 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. This drug is a complex mixture of polysaccharide chains derived from naturally sourced heparin. Our second major generic product candidate is ***M356***, a technology-enabled generic version of Copaxone® (glatiramer acetate injection), a drug that is indicated for the reduction of the frequency of relapses in patients with Relapse-Remitting Multiple Sclerosis, or RRMS. Copaxone consists of a complex mixture of polypeptide chains. With M356, we have extended our core characterization capabilities from the characterization of complex polysaccharide mixtures to include the characterization of complex polypeptide mixtures.

In addition to our two complex generic product candidates, which are both currently under review by FDA, we have further extended our analytical and development platform to pursue generic or follow-on versions of biologic drugs. Our efforts on ***M178***, as well as our ongoing ***Glycoprotein Research Program***, are focused on developing generic or follow-on versions of marketed therapeutic proteins, which are derived from natural or cell based manufacturing processes. By thoroughly characterizing these biologic molecules, we seek to gain a deeper understanding of the relationship between their manufacturing processes and final product compositions. Our goal is to replicate our development

approach with M-Enoxaparin and M356 and pursue the development and commercialization of multiple generic or follow-on versions of marketed therapeutics.

Our complex mixture novel drug research and development efforts leverage our analytical technology platform and *structure-process* knowledge to develop novel drugs by studying the *structure-activity* of complex mixtures and develop novel drugs. With our capabilities to thoroughly characterize complex mixtures, we are targeting our efforts to understand the relationship between structure and the biological and therapeutic activity of various complex mixture drugs. Our goal is to capitalize on the structural diversity and multi-targeting potential of these complex mixtures to engineer novel drugs that we believe will meet key unmet medical needs in various diseases. While we believe that our capabilities to engineer improved and novel complex mixture drugs can be applied across several product categories with significant therapeutic potential, such as polysaccharides, polypeptides and glycoproteins, our initial focus has been in the area of complex polysaccharide mixtures.

Our lead novel 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. We also are seeking to discover and develop novel therapeutics by applying our technology to better understand the function of these polysaccharide mixtures in biological processes, with an initial focus in oncology.

Since our inception in May 2001, we have incurred annual net losses. As of December 31, 2008, we had an accumulated deficit of $257.0 million. We recognized net losses of $62.6 million, $68.9 million and $51.9 million for the years ended December 31, 2008, 2007 and 2006, 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, 2008, 2007 and 2006 of $14.6 million, $21.6 million and $16.0 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. In June 2004, we completed an initial public offering of 6,152,500 shares of common stock, the net proceeds of which were $35.3 million after deducting underwriters' discounts and expenses. In July 2005, we raised $122.3 million in a follow-on public offering, net of expenses, from the sale and issuance of 4,827,300 shares of our common stock. In September 2006, in connection with the 2006 Sandoz Collaboration, we sold 4,708,679 shares of common stock to Novartis Pharma AG for an aggregate purchase price of $75.0 million. In December 2008, we raised $24.1 million in a public offering, net of expenses, from the sale and issuance of 2,800,000 shares of our common stock. 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, $74.4 million of revenue from our inception through December 31, 2008. 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, contract research and manufacturing, 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. Lovenox is a widely-prescribed LMWH used for the prevention and treatment of deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or 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. Both ANDAs currently include a Paragraph IV certification stating that Sanofi-Aventis' patents listed in the Orange Book for Lovenox are, among other things, invalid and unenforceable.

The FDA is currently reviewing both M-Enoxaparin ANDAs, including our manufacturing data and technology and characterization methodology. In November 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin was not approvable in its current form because the ANDA did not adequately address the potential for immunogenicity of the drug product. Starting in early 2008, we and Sandoz conferred with the FDA concerning the design of studies to address the FDA's concerns in this area. These interactions led to the FDA's general concurrence with our proposed approach and to the submission of an immunogenicity amendment to the M-Enoxaparin ANDA in September, 2008. Although the ANDA review process is ongoing, the FDA has not requested human clinical trials at this time. However, there can be no assurances that the FDA will not require such 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 working together to prepare for the commercialization of M-Enoxaparin, if and when approved, by advancing manufacturing, supply chain, and sales and marketing objectives.

Our 2006 Sandoz Collaboration expanded our collaboration efforts related to M-Enoxaparin to include the European Union. Under the 2006 Sandoz Collaboration, we will share certain development, regulatory, legal and commercialization costs as well as a portion of the profits, if any.

M356

M356 is designed to be a technology-enabled 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 Relapse-Remitting Multiple Sclerosis. Multiple sclerosis is a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. In North America, Copaxone is marketed through Teva Neuroscience LLC, a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., and distributed by Sanofi-Aventis. Teva and Sanofi-Aventis have an additional collaborative arrangement for the marketing of Copaxone in Europe and other markets, under which Copaxone is either co-promoted with Teva or is marketed solely by Sanofi-Aventis. Under the Definitive Agreement, we and Sandoz jointly develop, manufacture and commercialize M356. We are responsible for funding substantially all of the U.S.-related M356 development costs, with Sandoz responsible for legal and commercialization costs. Outside of the U.S., we and Sandoz share equally the development costs, with Sandoz responsible for commercialization and legal costs.

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' ANDA eligible for the grant of a 180-day generic exclusivity period upon approval.

M118

M118 is a novel anticoagulant that 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 October 2007, we began 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. We expect enrollment in the Phase 2a clinical trial to conclude in the second quarter of 2009.

In March 2007, we filed 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.

Glycoproteins

Glycoproteins are proteins to which sugar molecules are attached. Examples of glycoprotein drugs are erythropoietin, blood clotting factors and interferon beta. We are applying our technology to the development of generic or biosimilar glycoprotein drugs. We believe that this technology can further be used in assisting pharmaceutical and biotechnology companies in developing improved and next-generation versions of their branded products by analyzing and modifying the sugar structures contained in the branded products, and can also be used to engineer novel complex mixture drugs.

Our glycoprotein program is focused on extending our technology for the analysis of complex sugars to glycoproteins. The goal of the program is to facilitate the development of generic or biosimilar versions of major marketed glycoprotein drugs.

Under our 2006 Sandoz Collaboration, we are currently applying our technology to develop a generic or follow-on version of a marketed glycoprotein in partnership with Sandoz. We refer to this product candidate as M178.

Discovery Program

We are also applying our analytical capabilities to drug discovery. Our discovery program is focused on the role that complex sugars play in biological systems, including regulating the development and progression of disease. Our initial focus is in the area of cancer, where we are seeking to discover sugar sequences with anti-cancer properties for development as therapeutics, and we are advancing an oncology product candidate that is in the advanced discovery phase. Sugars play a part in the conversion of normal cells into cancerous cells, the regulation of tumor growth and tumor invasion and metastasis. We believe that our technology can provide us with a better understanding of the role of sugars in disease, enabling us to discover novel sugar therapeutics, as well as to discover new disease mechanisms that can be targeted with other small molecule and biologic drugs.

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, 2008, 2007 and 2006

Revenue

Revenue for 2008 was $14.6 million, compared with $21.6 million for 2007 and $16.0 million for 2006. Revenue for the year ended December 31, 2008 consists of amounts earned by us under our 2003 Sandoz Collaboration for reimbursement of research and development services, reimbursement of development costs and amortization of the initial payment received 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 decreased $7.0 million from 2007 to 2008 due primarily to a $7.0 million 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.

Revenue increased $5.6 million from 2006 to 2007 due primarily to $2.7 million of reimbursable expenditures associated with the first year of the 2006 Sandoz Collaboration, a $1.7 million increase in

reimbursable development expenditures associated with preparing for the potential commercial launch of M-Enoxaparin in the U.S., and $1.2 million of the first year of amortization related to the equity premium.

Research and Development

Research and development expense for 2008 was $55.3 million, compared with $69.9 million in 2007 and $46.9 million in 2006. 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 associated with the growth in our research and development organization, $0.7 million in laboratory expenses and $0.7 million in depreciation expense. The increase of $23.0 million, or 49%, from 2006 to 2007 principally resulted from: increases of $8.5 million in manufacturing, process development and third-party research costs in support of our M356, M-Enoxaparin and glycoprotein programs; $5.6 million in clinical trial costs for our M118 program; $5.2 million in personnel and related costs associated with the growth in our research and development organization; $1.4 million in laboratory supplies; and a $0.7 million in-process research and development charge related to the Parivid asset purchase.

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, 2008, 2007, and 2006, 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. The Company does not maintain or evaluate, and therefore does not allocate, internal research and development costs on a project-by-project basis. Consequently, the Company does not analyze internal research and development costs by project in managing its research and development activities.

Research and Development Expense (in thousands)	2008	2007	2006	Project Inception to December 31, 2008
Development programs (Status)				
M-Enoxaparin (ANDA Filed)	$ 3,855	$13,078	$ 9,108	$39,863
M356 (ANDA Filed)	4,401	8,105	3,364	16,005
M118 (Phase 2a)	9,886	10,945	6,282	29,628
Other development programs	589	442	154	1,524
Discovery programs	664	997	449	2,233
Research and development internal costs	35,906	36,332	27,559	
Total research and development expense	$55,301	$69,899	$46,916	

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 increase of $4.0 million in external expenditures related to our M-Enoxaparin program from 2006 to 2007 was primarily due to increased process development, manufacturing costs and third-party research. The increase in external expenditures on our M356 program of $4.7 million from 2006 to 2007 was primarily related to drug process work and the investment required to support the ANDA filing at the end of 2007. The increase of $4.7 million in external expenditures on our M118 program from 2006 to 2007 was primarily attributable to increased clinical costs as we progressed from preclinical to Phase 1 and Phase 2a clinical studies.

The research and development internal costs, which consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation, remained relatively consistent from 2007 to 2008. The increase of $8.8 million from 2006 to 2007 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, 2008 was $24.6 million, compared to $28.2 million in 2007 and $28.5 million in 2006. 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. General and administrative expense decreased by $0.3 million, or 1%, from 2006 to 2007 primarily due to a decrease of $1.8 million in professional fees due to a reduction in legal activities, offset by an increase of $1.5 million in personnel and related costs due to increased headcount.

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 $3.5 million, $8.5 million and $8.0 million for the years ended December 31, 2008, 2007 and 2006, respectively. The decrease of $5.0 million from 2007 to 2008 was primarily due to lower average investment balances and lower interest rates. The increase of $0.5 million from 2006 to 2007 was primarily due to higher average investment balances as a result of the proceeds from the issuance of common stock to Novartis Pharma AG in September 2006.

Interest Expense

Interest expense was $0.8 million, $0.8 million and $0.5 million for the years ended December 31, 2008, 2007 and 2006, respectively. The increase of $0.3 million from 2006 to 2007 was primarily due to additional amounts drawn from our equipment line of credit during 2006 and 2007.

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. 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, we completed a public offering and raised net proceeds of $24.1 million. As of December 31, 2008, we have received a cumulative total of $72.3 million from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, $4.0 million from debt financing, $9.2 million from capital lease obligations, $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 2010. 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, 2008, we had $108.5 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, 2008, 2007 and 2006, our operating activities used $48.4 million, $56.3 million and $25.2 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. Non-cash items include stock based compensation of $9.2 million, depreciation and amortization of $4.4 million and accretion of discount on investments of $2.0 million. 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 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 to the amortization of the $13.6 million equity premium.

For the year ended December 31, 2006, our net loss adjusted for non-cash items was $40.1 million. In addition, the net change in our operating assets and liabilities provided $14.9 million, primarily due to an increase in deferred revenue of $13.4 million relating to the equity premium offset by the restriction of $2.9 million in conjunction with a letter of credit for a sublease. Remaining increases of approximately $3.7 million in accounts payable and accrued expenses were due to general increases in our business activities as a result of greater headcount and increased product development costs.

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. Net cash used in investing activities was $46.3 million for the year ended December 31, 2006. During 2006, we used $243.2 million of cash to purchase marketable securities, offset by cash provided of $206.6 million in maturities of marketable securities. During the years ended December 31, 2008, 2007 and 2006, we used $3.4 million, $8.8 million and $9.8 million, respectively, to purchase laboratory equipment and leasehold improvements.

Net cash provided by financing activities for the year ended December 31, 2008 was $22.3 million. We received net proceeds of $24.1 million from our public offering of common stock in December 2008 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 lease agreement obligations and $0.6 million on financed leasehold improvements related to our corporate facility. Net cash provided by financing activities for the year ended December 31, 2007 was $6.1 million. We borrowed $4.2 million on an equipment lease agreement entered into in December 2005, 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, offset by principal payments of $2.1 million on our line of credit and lease agreement obligations and payments of $0.6 million on financed leasehold improvements. Net cash provided by financing activities for the year ended December 31, 2006 was $68.0 million. We received net proceeds of $74.9 million from the sale of 4,708,679 shares of common stock to Novartis Pharma AG, of which $13.6 million was classified as deferred revenue. Additionally, we borrowed $3.7 million on an equipment lease agreement, received $3.2 million in financing from our landlord for leasehold improvements related to our corporate facility, and received proceeds of $1.3 million from stock option exercises and purchases of common shares through our employee stock purchase plan, offset by principal payments of $1.3 million on our line of credit and lease agreement obligations and payments of $0.3 million on financed leasehold improvements.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2008:

Contractual Obligations (in thousands)	Payments Due by Period		2010 through 2011	2012 through 2013	After 2013
	Total	2009			
License maintenance obligations	$ 763	$ 133	$ 315	$315	*
Short and long-term line of credit obligation	17	17	—	—	$—
Capital lease obligations	7,114	2,671	4,443	—	—
Operating lease obligations	8,580	3,650	4,930	—	—
Total contractual obligations	$16,474	$6,471	$9,688	$315	$—

* After 2013, the annual obligations, which extend indefinitely, are approximately $0.2 million per year.

We anticipate that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations through at least 2010. 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.

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, accrued expenses and certain equity instruments. Prior to our initial public offering, we also evaluated our estimates and judgments regarding the fair valuation assigned to our common stock. 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 record revenue on an accrual basis as it is earned and when amounts are considered collectible. Revenues 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.

Revenue from milestone payments that represent the culmination of a separate earnings process are recorded when the milestone is achieved.

Cash, Cash Equivalents, and Marketable Securities

We invest our excess cash in bank deposits, money market accounts, corporate debt securities, commercial paper and U.S. government sponsored enterprise obligations. We consider all highly liquid

investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and primarily consist of money market funds maintained at major U.S. financial institutions. All marketable securities, which primarily represent marketable debt securities, have been classified as "available-for-sale." 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. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income. 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, 2007 or 2006. The cost of securities sold is based on the specific identification method. Interest earned on marketable securities is included in interest income.

Intangible Assets

We have acquired intangible assets that we value and record. Those assets for which there are no alternative uses are expensed as acquired in-process research and development, and those that are specifically identified and have alternative future uses are capitalized. 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.

Fair Value of other Financial Instruments

The carrying amounts of our other financial instruments, which include 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.

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 adopted the Financial Accounting Standards Board's, or FASB, Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), *Share Based Payment*, or SFAS 123R, effective January 1, 2006 under the modified prospective transition method. SFAS 123R requires the recognition of the fair value of stock-based compensation expense in our operations, and accordingly the adoption of SFAS 123R fair value method has had and will continue to have a significant impact on our results of operations, although it will have no impact on our overall financial position.

Prior to January 1, 2006, we accounted for employee stock options under the recognition and measurement provisions of Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and provided pro forma disclosures of net loss attributable and net loss per share allocable to common stockholders as if we had adopted the fair value based method of accounting in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123.*

We determine 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. In determining our volatility, we have considered implied volatilities of currently traded options to provide an estimate of volatility based upon current trading activity in addition to our historical volatility. After considering other factors such as our stage of development and the length of time we have been public, 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. For purposes of identifying similar entities, we considered characteristics such as industry, stage of life cycle and financial leverage. 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. We will continually monitor employee exercise behavior and may further adjust the estimated term and forfeiture rates in future periods. Increasing the estimated life would result in an increase in the fair value to be recognized over the requisite service period, generally the vesting period. 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 risk-free interest rates used in the Black-Scholes-Merton option pricing model are based on the United States Treasury yield curve in effect for periods corresponding with the expected term of the stock option.

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 June 2008, we revised the implicit service period for certain performance-based restricted stock awards due to a change in the expected vesting date. As a result of this change in estimate, our net loss and net loss per share for the year ended December 31, 2008 was $0.2 million and $0.01 per share, respectively, less than had the estimate remained unchanged.

For the years ended December 31, 2008, 2007 and 2006, we recognized total stock-based compensation expense under SFAS 123R of $9.2 million, $12.7 million and $11.4 million, respectively. As of December 31, 2008, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $11.8 million, including estimated forfeitures, which will be amortized over the weighted-average remaining requisite service periods of 2.4 years. As of December 31, 2008, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $4.2 million, including estimated forfeitures, which will be amortized over the weighted-average remaining requisite service periods of approximately 1.4 years.

Recently Issued Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, or SFAS 141(R), a replacement for SFAS No. 141, *Business Combinations*. SFAS 141(R) retains the fundamental requirements of SFAS No. 141, but requires the recognition of all assets acquired and liabilities assumed in a business combination at their fair values as of the acquisition date. It also requires the recognition of assets acquired and liabilities assumed arising from contractual contingencies at their acquisition date fair values. Additionally, SFAS 141(R) supersedes FASB Interpretation, or FIN, No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, which required research and development assets acquired in a business combination that have no alternative future use to be measured at their fair values and expensed at the acquisition date. SFAS 141(R) now requires that purchased research and development be recognized as an intangible asset. We are required to adopt SFAS 141(R) prospectively for any acquisitions on or after January 1, 2009. We do not expect the adoption of SFAS 141(R) to have any impact on our results of operations, financial position or cash flows.

In December 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF 07-1. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products).* EITF 07-01 is effective for all of our collaborations existing after January 1, 2009. We do not currently believe the adoption of EITF 07-1 will have a material impact on our results of operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51,* or SFAS 160. SFAS 160 requires that noncontrolling interests be reported as a separate component of equity, that net income attributable to the parent and to the noncontrolling interest be separately identified in the consolidated statement of operations, that changes in a parent's ownership interest be accounted for as equity transactions, and that, when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary and the gain or loss on the deconsolidation of the subsidiary be measured at fair value. SFAS 160 will be applied prospectively, except for presentation and disclosure requirements which will be applied retrospectively, as of the beginning of our fiscal year 2010. We do not currently have any noncontrolling interests, and therefore the adoption of SFAS 160 is not expected to have an impact on our results of operations, financial position or cash flows.

In February 2008, the FASB issued Staff Position, or FSP, No. 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2, which delays the effective date of Statement No. 157 for all nonfinancial assets and nonfinancial liabilities, except for those that are recognized or disclosed at fair value in the financial statements on a recurring basis. We are required to apply the provisions of

Statement No. 157 to nonfinancial assets and nonfinancial liabilities as of January 1, 2009. We do not believe the adoption of FSP 157-2 will have a material impact on our future results of operations or financial position.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*, or SFAS 161. SFAS 161 enhances the disclosure requirements for derivative instruments and hedging activities. SFAS 161 was effective January 1, 2009. Since SFAS 161 requires only additional disclosures concerning derivatives and hedging activities, adoption of SFAS 161 will not affect our results of operations, financial position or cash flows given that we do not engage in derivative or hedging activities.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with accounting principles generally accepted in the United States. We do not expect the adoption of SFAS 162 to have a material impact on our consolidated financial statements.

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, 2008, 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

Momenta Pharmaceuticals, Inc.
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, 2008 and 2007, 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, 2008. 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, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 12 to the consolidated financial statements, effective January 1, 2007, the Company adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109.*

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, 2008, 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 10, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 10, 2009

Momenta Pharmaceuticals, Inc.

Consolidated Balance Sheets

	December 31,	
	2008	2007
	(In thousands, except per share amounts)	
Assets		
Current assets:		
Cash and cash equivalents	$ 55,070	$ 33,038
Marketable securities	53,461	102,899
Accounts receivable	455	747
Unbilled collaboration revenue	2,372	9,037
Prepaid expenses and other current assets	1,217	1,984
Total current assets	112,575	147,705
Property and equipment, net of accumulated depreciation	14,725	15,296
Intangible assets, net	3,111	3,495
Restricted cash	1,778	1,778
Other assets	12	24
Total assets	$ 132,201	$ 168,298
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,578	$ 9,132
Accrued expenses	6,744	5,973
Deferred revenue	2,150	2,180
Line of credit obligations	17	721
Capital lease obligations	1,846	1,696
Lease financing liability	687	640
Deferred rent	70	70
Other current liabilities	2,000	2,000
Total current liabilities	19,092	22,412
Deferred revenue, net of current portion	8,063	10,212
Capital lease obligations, net of current portion	4,427	6,273
Lease financing liability, net of current portion	995	1,681
Other long term liabilities	119	180
Total liabilities	32,696	40,758
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Preferred stock, $0.01 par value; 5,000 shares authorized at December 31, 2008 and 2007, 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, 2008 and 2007, 39,691 and 36,489 shares issued and outstanding at December 31, 2008 and 2007, respectively	4	4
Additional paid-in capital	356,124	321,604
Accumulated other comprehensive income	414	332
Accumulated deficit	(257,037)	(194,400)
Total stockholders' equity	99,505	127,540
Total liabilities and stockholders' equity	$ 132,201	$ 168,298

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

Momenta Pharmaceuticals, Inc.

Consolidated Statements of Operations

	Year Ended December 31,		
	2008	2007	2006
	(In thousands, except per share amounts)		
Collaboration revenue	$ 14,570	$ 21,561	$ 15,999
Operating expenses:			
Research and development*	55,301	69,899	46,916
General and administrative*	24,591	28,219	28,466
Total operating expenses	79,892	98,118	75,382
Loss from operations	(65,322)	(76,557)	(59,383)
Other income (expense):			
Interest income	3,483	8,484	7,974
Interest expense	(798)	(808)	(504)
Net loss	$(62,637)	$(68,881)	$(51,913)
Basic and diluted net loss per share	$ (1.74)	$ (1.93)	$ (1.62)
Shares used in computing basic and diluted net loss per share	35,960	35,639	32,103
* Includes stock-based compensation as follows:			
Research and development	$ 3,124	$ 4,792	$ 4,367
General and administrative	$ 6,090	$ 7,895	$ 7,035

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)	Deferred Stock Compensation	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value					
Balances at December 31, 2005	30,465	$ 3	$236,190	$(239)	$(2,193)	$ (73,606)	$160,155
Issuance of common stock to Sandoz	4,709	1	61,383	—	—	—	61,384
Issuance of common stock pursuant to the exercise of stock options and employee stock purchase plan	379	—	1,279	—	—	—	1,279
Issuance of restricted stock	745	—	—	—	—	—	—
Cancellation of restricted stock	(200)	—	—	—	—	—	—
Reclassification of unearned compensation on non-vested share awards upon adoption of SFAS 123R	—	—	(2,193)	—	2,193	—	—
Stock-based compensation expense for employees	—	—	11,130	—	—	—	11,130
Stock-based compensation expense for non-employees	—	—	272	—	—	—	272
Unrealized gain on marketable securities	—	—	—	284	—	—	284
Net loss	—	—	—	—	—	(51,913)	(51,913)
Comprehensive loss	—	—	—	—	—	—	(51,629)
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

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

Momenta Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2008	2007	2006
	(In thousands)		
Cash Flows from Operating activities:			
Net loss	$ (62,637)	$ (68,881)	$ (51,913)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3,975	3,308	1,947
Stock-based compensation expense	9,214	12,687	11,402
Loss on disposal of assets	7	92	147
Accretion of discount on investments	(2,047)	(5,907)	(1,702)
Realized gain on sales of marketable securities	(47)	—	—
Charge for in-process research and development	—	737	—
Amortization of intangibles	384	268	—
Changes in operating assets and liabilities:			
Accounts receivable	292	(747)	—
Unbilled collaboration revenue	6,665	(4,310)	(380)
Prepaid expenses and other current assets	767	85	730
Restricted cash	—	2,907	(2,907)
Other assets	12	12	(30)
Accounts payable	(3,554)	4,821	1,231
Accrued expenses	771	187	2,431
Deferred rent	(70)	(312)	429
Deferred revenue	(2,179)	(1,283)	13,405
Other long term liabilities	26	—	—
Net cash used in operating activities	(48,421)	(56,336)	(25,210)
Cash Flows from Investing activities:			
Purchase of intangible assets	—	(2,500)	—
Purchases of marketable securities	(120,527)	(242,526)	(243,176)
Proceeds from maturities of marketable securities	163,800	314,735	206,612
Purchase of property and equipment	(3,411)	(8,817)	(9,780)
Sales of marketable securities	8,341	—	—
Net cash provided by (used in) investing activities	48,203	60,892	(46,344)
Cash Flows from Financing activities:			
Proceeds from public offering of common stock, net of issuance costs	24,140	—	—
Proceeds from issuance of common stock to Sandoz, net of issuance costs	—	—	61,384
Proceeds from issuance of common stock under stock plans	1,166	856	1,279
Proceeds from financing of leasehold improvements	—	—	3,199
Payments on financed leasehold improvements	(639)	(596)	(282)
Principal payments on line of credit	(721)	(883)	(845)
Proceeds from capital lease obligations	—	4,199	3,735
Principal payments on capital lease obligations	(1,696)	(1,169)	(455)
Proceeds from assignment of sublease, net of recovery of rent expense	—	3,724	—
Net cash provided by financing activities	22,250	6,131	68,015
Increase (decrease) in cash and cash equivalents	22,032	10,687	(3,539)
Cash and cash equivalents, beginning of period	33,038	22,351	25,890
Cash and cash equivalents, end of period	$ 55,070	$ 33,038	$ 22,351
Supplemental Cash Flow Information:			
Cash paid for interest	$ 798	$ 808	$ 504
Non Cash Transactions:			
Accrued milestone payments to Parivid	$ —	$ 2,000	$ —

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 on May 17, 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, Cash Equivalents, and Marketable Securities

The Company invests its excess cash in bank deposits, money market accounts, corporate debt securities, commercial paper and U.S. government sponsored enterprise obligations. The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and primarily consist of money market funds maintained at major U.S. financial institutions. All marketable securities, which primarily represent marketable debt securities, have been classified as "available-for-sale." Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. Management 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. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income. 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, 2007 or 2006. The cost of securities sold is based on the specific identification method. Interest earned on marketable securities is included in interest income.

Credit Risks and Concentrations

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and marketable securities. The Company has established guidelines relating to diversification and maturities that allow the Company to manage risk.

Fair Value of Other Financial Instruments

The carrying amounts of the Company's other financial instruments, which include other accrued expenses, approximate their fair values due to their short maturities. The carrying amount of the Company's line of credit and capital lease obligations approximate their fair values due to their variable interest rates.

Unbilled Collaboration Revenue

Unbilled collaboration revenue represents amounts owed from one collaborative partner at December 31, 2008 and December 31, 2007. 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 in accordance with the provisions of the Financial Accounting Standards Board's ("FASB") Statement of Financial Accounting Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS 144, which provides that companies (1) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (2) measure an impairment loss as the difference between the carrying amount and fair value of the asset. 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. In addition, SFAS 144 provides guidance on accounting and disclosure issues surrounding long-lived assets to be disposed of by sale. No impairment charges have been required to be recognized through December 31, 2008.

Revenue Recognition

The Company recognizes revenue from research and development collaboration agreements in accordance with the U.S. Securities and Exchange Commission's ("SEC") Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force ("EITF") Issue No. 00-21, *Revenue Arrangements With Multiple Deliverables.*

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.

Revenues 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 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 in accordance with EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, which was adopted by the Company effective January 1, 2008. The adoption of EITF 07-03 did not have an impact on our results of operations, financial position or cash flows. The capitalized amounts are expensed as the related goods are delivered or the services are received.

Stock-Based Compensation Expense

As discussed more fully in Note 3, the Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123R, effective January 1, 2006 under the modified prospective transition method of adoption. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, is being recognized in the Company's statements of operations in the periods after the date of adoption over the remaining vesting periods, if any. 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.

In accordance with SFAS 123R, the fair value of each option award was estimated 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.

SFAS 123R requires the application of 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 have been revalued using the Company's estimate of fair value at each balance sheet date pursuant to EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Stock-based compensation expense is recorded in accordance with FASB Interpretation ("FIN") No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, or FIN 28.

Income Taxes

The Company accounts for income taxes under SFAS No. 109, *Accounting for Income Taxes*, or SFAS 109. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and 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 follows FIN No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*, or FIN 48, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

As a result of adopting FIN 48, as of January 1, 2007, the Company recorded a reduction in its deferred tax asset valuation allowance of approximately $3.1 million for unrecognized tax benefits related to research and development tax credit and net operating losses. During the years ended December 31, 2008 and 2007, the Company had $529,000 and $1.1 million of net additions to its unrecognized tax positions and its deferred tax assets under FIN 48, respectively. 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, 2008, 2007 and 2006.

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

The Company reports comprehensive loss in accordance with SFAS No. 130, *Reporting Comprehensive Income*, which establishes rules for the reporting and display of comprehensive income (loss) and its components. Accumulated other comprehensive income as of December 31, 2008 and December 31, 2007 consists entirely of unrealized gains and losses on available-for-sale securities. Comprehensive loss for the years ended December 31, 2008, 2007 and 2006 was $62.6 million, $68.6 million and $51.6 million, respectively.

Net Loss Per Share

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings per Share,* or SFAS 128. Under the provisions of SFAS 128, basic net loss per common share is computed 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 4,938,537, 3,981,601 and 3,273,386 for the years ended December 31, 2008, 2007 and 2006, respectively.

Segment Reporting

SFAS No. 131, *Disclosure about Segments of an Enterprise and Related Information*, requires companies to report selected information about operating segments, as well as enterprise-wide disclosures about products, services, geographical areas, and major customers. 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 drug products. All of the Company's revenues through December 31, 2008 have come from one collaborative partner.

Recently Issued Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, or SFAS 141(R), a replacement for SFAS No. 141, *Business Combinations.* SFAS 141(R) retains the fundamental requirements of SFAS No. 141, but requires the recognition of all assets acquired and liabilities assumed in a business combination at their fair values as of the acquisition date. It also requires the recognition of assets acquired and liabilities assumed arising from contractual contingencies at their acquisition date fair values. Additionally, SFAS 141(R) supersedes FIN No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, which required research and development assets acquired in a business combination that have no alternative future use to be measured at their fair values and expensed at the acquisition date. SFAS 141(R) now requires that purchased research and development be recognized as an intangible asset. The Company is required to adopt SFAS 141(R) prospectively for any acquisitions on or after January 1, 2009. The

Company does not expect the adoption of this pronouncement will have any impact on its results of operations, financial position or cash flows.

In December 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements,* or EITF 07-1. EITF 07-1 requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. Further, EITF 07-1 clarified the determination of whether transactions within a collaborative arrangement are part of a vendor-customer (or analogous) relationship subject to EITF Issue No. 01-9, *Accounting for Consideration given by a Vendor to a Customer (Including a Reseller of the Vendor's Products).* EITF 07-1 will be effective for the Company beginning on January 1, 2009. The Company does not currently believe the adoption of EITF 07-1 will have a material impact on its results of operations, financial position or cash flows.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51*, or SFAS 160. SFAS 160 requires that noncontrolling interests be reported as a separate component of equity, that net income attributable to the parent and to the noncontrolling interest be separately identified in the consolidated statement of operations, that changes in a parent's ownership interest be accounted for as equity transactions, and that, when a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary and the gain or loss on the deconsolidation of the subsidiary be measured at fair value. SFAS 160 will be applied prospectively, except for presentation and disclosure requirements which will be applied retrospectively, as of the beginning of the Company's fiscal year 2010. The Company does not currently have noncontrolling interests, and therefore does not expect the adoption of SFAS 160 to have an impact on its results of operations, financial position or cash flows.

In February 2008, the FASB issued Staff Position ("FSP") No. 157-2, *Effective Date of FASB Statement No. 157*, or FSP 157-2, which delays the effective date of Statement No. 157 for all nonfinancial assets and nonfinancial liabilities, except for those that are recognized or disclosed at fair value in the financial statements on a recurring basis. The Company is required to apply the provisions of Statement No. 157 to nonfinancial assets and nonfinancial liabilities as of January 1, 2009. The Company does not believe the adoption of FSP 157-2 will have a material impact on its future results of operations or financial position.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*, or SFAS 161. SFAS 161 enhances the disclosure requirements for derivative instruments and hedging activities. SFAS 161 was effective January 1, 2009. Since SFAS 161 requires only additional disclosures concerning derivatives and hedging activities, adoption of SFAS 161 will not affect the Company's results of operations, financial condition or cash flows given that it does not engage in derivative or hedging activities.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. SFAS 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements that are presented in conformity with accounting principles generally accepted in the United States. The Company does not expect the adoption of SFAS 162 to have a material impact on its consolidated financial statements.

3. Stock-Based Compensation

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, 2008, the Company was authorized to issue up to 7,574,329 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. At December 31, 2008, the Company had 2,790,900 shares available for grant under the 2004 Stock Incentive Plan. Effective January 1, 2009, the Company's Board of Directors increased the number of authorized shares by 1,846,116 shares.

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.

SFAS 123R Compensation Expense

The Company adopted SFAS 123R effective January 1, 2006. SFAS 123R requires the recognition of the fair value of stock-based compensation in its statements 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 stock option plans and employee stock purchase plan.

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, 2008, 2007 and 2006 was $9.2 million, $12.7 million and $11.4 million, respectively. The Company recorded stock-based compensation expense of $6.7 million, $7.0 million and $5.9 million related to outstanding employee stock option grants for the years ended December 31, 2008, 2007 and 2006, respectively.

In accordance with SFAS 123R, 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 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 considered 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 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		
	2008	2007	2006	2008	2007	2006
Expected volatility	83%	76%	72%	80%	74%	68%
Expected dividends	—	—	—	—	—	—
Expected life (years)	6	6	6	0.5	0.5	0.5
Risk-free interest rate	3.29%	4.7%	4.8%	3.0%	4.8%	5.2%

SFAS 123R requires the application of 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 catch-up adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods.

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, 2008, the Company had 383,679 shares available for grant under the ESPP. The Company issued 51,691 shares of common stock to employees under the plan during the year ended December 31, 2008. The ESPP is accounted for under SFAS 123R. During each of the years ended December 31, 2008, 2007 and 2006, the Company recorded stock-based compensation expense of $0.2 million with respect to the ESPP. At December 31, 2008, subscriptions were outstanding for an estimated 14,264 shares at a fair value of approximately $6.37 per share. The weighted average grant date fair value of the offerings during 2008, 2007 and 2006 was $3.98, $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, 2008:

	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, 2008	3,194	$12.02		
Granted	1,145	9.59		
Exercised	(141)	5.90		
Forfeited	(236)	16.28		
Expired	(8)	27.38		
Outstanding at December 31, 2008	3,954	$11.26	7.29	$9,415
Exercisable at December 31, 2008	2,325	$11.03	6.34	$6,267
Vested or expected to vest at December 31, 2008	3,795	$11.30	7.22	$9,001

The weighted average grant date fair value of options granted during 2008, 2007 and 2006 was $6.92, $7.90 and $11.50 per option, respectively. The total intrinsic value of options exercised during 2008, 2007 and 2006 was $1.1 million, $1.0 million and $4.9 million, respectively. At December 31, 2008, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $11.8 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.4 years. The total fair value of shares vested during 2008, 2007 and 2006 was $6.2 million, $7.3 million and $7.0 million, respectively.

Cash received from option exercises for 2008, 2007 and 2006 was $0.8 million, $0.4 million and $1.0 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, 2008, the Company awarded 251,760 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.

A summary of the status of nonvested shares of restricted stock as of December 31, 2008, 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, 2008	789	$19.68
Granted	252	8.18
Vested	(13)	11.17
Forfeited	(43)	18.74
Nonvested at December 31, 2008	985	$16.89

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of December 31, 2008 are summarized below:

Vesting Schedule	Nonvested Shares (in thousands)
Time-based	570
Performance-based	415
Nonvested at December 31, 2008	985

In June 2008, the Company revised the implicit service period for certain performance-based restricted stock awards due to a change in the expected vesting date. As a result of this change in estimate, the Company's net loss and net loss per share were $0.2 million and $0.01 per share, respectively, less than had the estimate remained unchanged for the year ended December 31, 2008. The total fair value of shares of restricted stock vested during 2008, 2007 and 2006 was $144,000, $64,000 and zero, respectively. The Company recorded stock-based compensation expense of $2.3 million, $5.4 million and $5.0 million related to outstanding restricted stock awards during 2008, 2007 and 2006, respectively. As of December 31, 2008, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $4.2 million, including estimated forfeitures, which is expected to be recognized over the weighted average remaining requisite service period of 1.4 years.

Stock Options Granted to Non-Employee Consultants

As of December 31, 2008, the Company had granted stock options to purchase 154,162 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 2008, 8,000 stock options expired. As of December 31, 2008, all outstanding options are fully vested. The Company recorded a stock-based compensation expense, using the accelerated method under FIN 28, of zero, $5,000 and $0.3 million during 2008, 2007 and 2006, 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 three to ten years, volatility of approximately 72% to 76% and risk free interest rates ranging from 4.2% to 5.0%.

4. 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' 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, $0.1 million and $0.1 million for the years ended December 31, 2008, 2007 and 2006, respectively.

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). Revenues 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 manufacturing raw material purchases, which are recorded on a net basis as an offset to the related development expense pursuant to the provisions of EITF Issue No. 02-16, *Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor.* The Company purchased $3.3 million of manufacturing raw material in 2006. There were no such manufacturing raw material purchases during 2008 or 2007.

2006 Sandoz Collaboration

In July 2006, the Company entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement, each with Novartis Pharma AG, and a Memorandum of Understanding (the "MOU") with Sandoz AG, an affiliate of Novartis Pharma AG. On June 13, 2007, the Company and Sandoz AG executed a definitive collaboration and license agreement (the "Definitive Agreement"), which superseded the MOU. 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 and $1.2 million for the years ended December 31, 2008 and 2007, respectively. 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. Each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all medical indications in the relevant regions. The Company has agreed to provide development and related services on a commercially reasonable basis, which includes developing a manufacturing process to make the products, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and 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 $178 million in milestone payments if all milestones are achieved for the three 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 $107,500, $82,500 and $487,500 related to these agreements in the years ended December 31, 2008, 2007 and 2006, 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.

5. Cash, Cash Equivalents, and Marketable Securities

The following is a summary of cash, cash equivalents, and marketable securities as of December 31, 2008 and 2007 (in thousands):

December 31, 2008	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

December 31, 2007	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 24,070	$ —	$—	$ 24,070
Corporate debt securities due in one year or less	44,291	45	(3)	44,333
Commercial paper obligations due in one year or less	67,244	290	—	67,534
Total	$135,605	$335	$(3)	$135,937
Reported as:				
Cash and cash equivalents	$ 33,025	$ 13	$—	$ 33,038
Marketable securities	102,580	322	(3)	102,899
Total	$135,605	$335	$(3)	$135,937

The Company reviews its investments for other than temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying value is not recoverable within a reasonable period of time. At December 31, 2008, no marketable securities are in an unrealized loss position. At December 31, 2007, there were three marketable securities in an unrealized loss position for less than one year. The unrealized losses were caused by fluctuations in interest rates. At December 31, 2007, there were no marketable securities in an unrealized loss position for greater than one year. The following table summarizes the aggregate fair value of these securities at December 31, 2007. The Company reviewed its investments with unrealized losses and has concluded that no other-than-temporary impairment existed at December 31, 2007 as the Company has the ability and intent to hold these investments to maturity.

	2007	
(in thousands)	Aggregate Fair Value	Unrealized Losses
Corporate debt securities due in one year or less	$4,508	$(3)

The Company recorded realized gains on marketable securities of $47,000 during the year ended December 31, 2008. The Company had no realized gains or losses during the years ended December 31, 2007 or 2006.

6. Fair Value Measurements

The Company adopted SFAS No. 157, *Fair Value Measurements*, or SFAS 157, as of January 1, 2008 and the adoption did not have a material impact on the consolidated financial position, results of operations or cash flows of the Company. In accordance with the provisions of FSP 157-2, the Company elected to defer implementation of SFAS 157 as it relates to non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. The Company anticipates that SFAS 157 will not have a material impact on its non-financial assets and liabilities.

SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with U.S. GAAP and enhances disclosure requirements for fair value measurements. SFAS 157 establishes 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 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.

Assets measured at fair value on a recurring basis at December 31, 2008 are as follows:

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	53,461	—	53,461	—
Total	$103,967	$50,506	$53,461	$—

The Company also adopted the provisions of SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an Amendment of FASB Statement No. 115,* or SFAS 159, during 2008. SFAS 159 allows the Company to choose to measure eligible assets and liabilities at fair value with changes in value recognized in earnings. Fair value treatment may be elected either upon initial recognition of an eligible asset or liability or, for an existing asset or liability, if an event triggers a new basis of accounting. The Company did not elect to re-measure any of its existing financial assets or liabilities under the provisions of SFAS 159.

7. Property and Equipment

At December 31, 2008 and 2007, property and equipment, net consists of the following (in thousands):

	2008	2007	Depreciable Lives
Computer equipment	$ 382	$ 250	3 years
Software	2,708	2,223	3 years
Office furniture and equipment	905	877	5 to 6 years
Laboratory equipment	6,170	3,722	7 years
Leasehold improvements	4,570	4,384	Shorter of asset life or lease term
Equipment purchased under capital lease obligations	10,061	10,061	3 to 7 years
Less: accumulated depreciation	(10,071)	(6,221)	
	$ 14,725	$15,296	

Depreciation and amortization expense, including amortization of assets recorded under capital leases, amounted to $4.0 million, $3.3 million and $1.9 million for the years ended December 31, 2008, 2007 and 2006, respectively.

8. Intangible Assets

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

		December 31, 2008		December 31, 2007	
	Estimated Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Core technology	12 years	$3,593	$(508)	$3,593	$(209)
Non-compete agreement	2 years	170	(144)	170	(59)
Total intangible assets		$3,763	$(652)	$3,763	$(268)

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

9. Restricted Cash

In September 2004, $1.5 million of the Company's cash was 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. In December 2005, this balance was increased to $1.8 million due to an increase in leased space.

In October 2006, an additional $2.9 million of the Company's cash was designated as collateral for a letter of credit related to the lease of additional office and laboratory space. In July 2007, as a result of an evaluation of its space needs the Company determined the additional office and laboratory space leased, but not yet occupied, was in excess of the Company's present requirements. In October 2007, the Company cancelled the letter of credit associated with the additional office and laboratory space, in connection with the assumption of the related lease agreement by a third party as discussed in Note 14, and reclassified $2.9 million from restricted cash to cash and cash equivalents.

10. Accrued Expenses

At December 31, 2008 and 2007, accrued expenses consisted of the following (in thousands):

	2008	2007
Accrued compensation	$3,208	$2,923
Accrued contracted research costs	2,476	2,205
Accrued professional fees	773	548
Other	287	297
	$6,744	$5,973

11. Common Stock

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.

12. Income Taxes

A reconciliation of the federal statutory income tax provision to the Company's actual provision for the years ended December 31, 2008, 2007 and 2006 is as follows:

	2008	2007	2006
Benefit at federal statutory tax rate	$(21,304)	$(23,381)	$(17,651)
State taxes, net of federal benefit	(3,927)	(4,319)	(3,255)
Change in valuation allowance	25,139	27,892	18,573
Stock-based compensation	662	810	3,669
Tax credits	(601)	(1,021)	(1,354)
Other	31	19	18
Income tax provision	$ —	$ —	$ —

At December 31, 2008, the Company had federal and state net operating loss carryforwards of $183.0 million and $192.0 million available, respectively, to reduce future taxable income and which will expire at various dates through 2028. Of this amount, approximately $4.5 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, 2008, federal and state research and development and other credit carryforwards were $3.3 million and $2.4 million, respectively, available to reduce future tax liabilities, and, which will expire at various dates beginning in 2016 through 2028.

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,	
	2008	2007
Deferred tax assets:		
Federal and state net operating losses	$ 70,611	$ 50,302
Research credits	4,827	4,341
Deferred compensation	9,942	7,881
Deferred revenue	4,011	4,990
Accrued expenses	201	150
Intangibles	437	360
Capital leases	3,124	4,144
Total deferred tax assets	93,153	72,168
Deferred tax liabilities:		
Depreciation	(3,754)	(4,856)
Unrealized gain on marketable securities	(144)	(116)
Total deferred tax liabilities	(3,898)	(4,972)
Valuation allowance	(89,255)	(67,196)
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 $22.1 million for the year ended December 31, 2008, primarily as a result of the current period loss.

Effective January 1, 2007, the Company adopted the provisions of FIN 48.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for the years ended December 31, 2008 and 2007 is as follows (in thousands):

	2008	2007
Balance, beginning of year	$4,425	$3,318
Additions for tax positions related to the current year	649	1,107
Additions of tax positions of prior years	—	—
Reductions of tax positions of prior years	(120)	—
Balance, end of year	$4,954	$4,425

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. As of December 31, 2007, the Company had $4.4 million of gross unrecognized tax benefits, $4.1 million of which, if recognized, would impact the Company's effective tax rate. The net increase in unrecognized tax benefits from 2007 to 2008 relates to research and development credits. 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 recognizes both accrued interest and penalties related to unrecognized tax benefits in income tax expense. The Company did not recognize any interest and penalties in the year ended December 31, 2008, or since the adoption of FIN 48.

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.

13. 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 are 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%.

14. Commitments and Contingencies

Capital and Operating Leases

In December 2005, the Company entered into a Master Lease Agreement (the "Agreement") with General Electric Capital Corporation ("GECC"). Under the Agreement, the Company may lease office, laboratory, computer and other equipment from GECC by executing specified equipment schedules with GECC. Each equipment schedule 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. 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, 2008, the Company had approximately $6.3 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 $5.0 million, $4.9 million and $5.4 million for the years ended December 31, 2008, 2007 and 2006, 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. In accordance with FSP No. 13-1, *Accounting for Rental Costs Incurred during a Construction Period*, 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. In accordance with EITF No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, the Company was the owner of the leasehold assets during the construction period, and as of December 31, 2008, the Company has recorded $3.2 million in leasehold improvements offset by $1.7 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, 2008 are as follows (in thousands):

	Operating Lease	Capital Lease
2009	$3,650	$ 2,671
2010	3,650	2,626
2011	1,280	1,817
2012	—	—
2013 and beyond		
Total future minimum lease payments	$8,580	7,114
Less—Amounts representing interest		(841)
Capital lease obligation at December 31, 2008		6,273
Less—Current maturities		(1,846)
Capital lease obligation, net of current maturities		$ 4,427

License Agreements

In connection with license arrangements with the research university discussed in Note 4, the Company has certain annual fixed obligations to pay fees for the technology licensed. At December 31, 2008, financial obligations under these agreements for 2009 amounted to $0.1 million. Beginning in 2010, the annual 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. 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.

15. 401(k) Plan

The Company has a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company has discretion to make contributions to the plan. In March 2005, the Company's Board of Directors approved a match of 50% of the first 6% contributed by employees, effective for the 2004 plan year and thereafter. The Company recorded $0.3 million, $0.4 million and $0.2 million of such match expense in the years ended December 31, 2008, 2007 and 2006, respectively.

16. Related Party Transactions

The Company purchased $3.3 million of heparin in 2006 from Sandoz GmbH, which in turn was reimbursed under the Company's collaboration agreement with Sandoz N.V. and Sandoz Inc. The Company did not purchase any heparin from Sandoz GmbH in 2008 or 2007. The Company did not have any outstanding payables to Sandoz at December 31, 2008 or 2007.

Parivid, LLC, 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 are achieved, will 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 milestone payments, which are probable and accrued at December 31, 2008 and 2007. 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 and $1.0 million as research and development expense related to work performed by Parivid in the years ended December 31, 2007 and 2006, respectively.

17. Selected Quarterly Financial Data (Unaudited) (in thousands, except per share data)

	Quarter Ended			
	March 31	June 30	September 30	December 31
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
2007				
Collaboration revenues	$ 2,242	$ 4,175	$ 5,145	$ 9,999
Net loss	(16,963)	(18,759)	(18,868)	(14,291)
Basic and diluted net loss per common share	$ (0.48)	$ (0.53)	$ (0.53)	$ (0.40)
Shares used in computing basic and diluted net loss per share	35,584	35,613	35,664	35,695

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, 2008. 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, 2008, 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, 2008. 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, 2008, 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 (the "Company") internal control over financial reporting as of December 31, 2008, 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, 2008, 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 as of December 31, 2008 and 2007, 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, 2008 of Momenta Pharmaceuticals, Inc. and our report dated March 10, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 10, 2009

(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, 2008 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 2009 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 amendments to, or waivers from, our code of business conduct and ethics that are 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 2009 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 2009 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 2009 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 2009 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 2009 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 13th day of March, 2009.

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 13, 2009
/s/ RICHARD P. SHEA Richard P. Shea	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2009
/s/ JAMES SULAT James Sulat	Chairman of the Board and Director	March 13, 2009
/s/ JOHN K. CLARKE John K. Clarke	Director	March 13, 2009
/s/ ALAN L. CRANE Alan L. Crane	Director	March 13, 2009
/s/ MARSHA H. FANUCCI Marsha H. Fanucci	Director	March 13, 2009
/s/ PETER BARTON HUTT Peter Barton Hutt	Director	March 13, 2009
/s/ ROBERT S. LANGER, JR. Robert S. Langer, Jr.	Director	March 13, 2009
/s/ RAM SASISEKHARAN Ram Sasisekharan	Director	March 13, 2009
/s/ BENNETT M. SHAPIRO Bennett M. Shapiro	Director	March 13, 2009
/s/ ELIZABETH STONER Elizabeth Stoner	Director	March 13, 2009

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	Second Amended and Restated Investors' Rights Agreement, dated as of February 27, 2004, by and among the Purchasers listed therein, the Founders listed therein and the Registrant; Amendment No. 1 to Second Amended and Restated Investors' Rights Agreement, dated as of June 10, 2004, by and among the Registrant and the Investors set forth therein	S-1/A	4.3	6/15/2004	333-113522
4.4	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

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.2†	Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant (the "November 1, 2002 M.I.T. License"); First Amendment to the November 1, 2002 M.I.T. License, dated November 15, 2002, by and between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated September 12, 2003, between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated October 22, 2003, between the Massachusetts Institute of Technology and the Registrant; Second Amendment to the November 1, 2002 M.I.T. License, dated November 19, 2003, by and between the Massachusetts Institute of Technology and the Registrant; Third Amendment to the November 1, 2002 M.I.T. License, dated April 2, 2004, by and between the Massachusetts Institute of Technology and the Registrant	8-K	10.1	8/15/2006	000-50797
10.3†	Letter Agreement Regarding November 1, 2002 M.I.T. License, dated August 4, 2006, between the Massachusetts Institute of Technology and the Registrant	8-K	10.1	8/15/2006	000-50797
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

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
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
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
	Material Contracts—Management Contracts and Compensation Plans				
10.17#	Amended and Restated 2002 Stock Incentive Plan	10-K	10.17	3/15/2007	000-50797
10.18#	2004 Stock Incentive Plan, as amended	10-K	10.18	3/15/2007	000-50797
10.19#	Form of Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.1	8/16/2004	000-50797
10.20#	Form of Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan	10-Q	10.2	8/16/2004	000-50797
10.21#	Form of Restricted Stock Agreement under 2004 Stock Incentive Plan	8-K	10.2	2/28/08	000-50797
10.22#	2004 Employee Stock Purchase Plan	S-1/A	10.3	4/16/2004	333-113522

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
10.23#	Non-Employee Director Compensation Summary	10-K	10.21	3/10/2008	000-50797
10.24#	Reallocation of Founder Shares Agreement, dated April 10, 2002, by and among Ganesh Venkataraman, Ram Sasisekharan, Robert S. Langer, Jr., Polaris Venture Partners III, L.P. and the Registrant	S-1	10.14	3/11/2004	333-113522
10.25#	Restricted Stock Agreement, dated March 7, 2006, between Ganesh Venkataraman and the Registrant	10-Q	10.14	11/8/2006	000-50797
10.26#	Employment Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.27#	Restricted Stock Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.8	11/8/2006	000-50797
10.28#	Nonstatutory Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.9	11/8/2006	000-50797
10.29#	Incentive Stock Option Agreement, dated August 22, 2006, between Craig Wheeler and the Registrant	10-Q	10.10	11/8/2006	000-50797
10.30#	Restricted Stock Agreement, dated March 7, 2006, between Steven B. Brugger and the Registrant	10-Q	10.13	11/8/2006	000-50797
10.31#	Restricted Stock Agreement, dated December 15, 2006, between John E. Bishop and the Registrant	10-K	10.56	3/15/2007	000-50797
10.32#	Restricted Stock Agreement, dated December 14, 2007, between John E. Bishop and the Registrant	10-K	10.35	3/10/2008	000-50797
10.33#	Restricted Stock Agreement, dated August 15, 2007, between Richard P. Shea and the Registrant	10-Q	10.1	11/08/2007	000-50797
10.34#	Restricted Stock Agreement, dated January 17, 2007, between Craig Wheeler and the Registrant	10-Q	10.7	11/8/2006	000-50797
10.35#	Form of Employment Agreement for executive officers	10-Q	10.3	5/9/2008	000-50797
10.36#	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
10.37#	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

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
	Material Contracts—Credit Agreements				
10.38	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
10.39	First Loan Modification Agreement, dated December 28, 2004, between Silicon Valley Bank and the Registrant	10-K	10.37	3/31/2005	000-50797
10.40	Loan and Security Agreement, dated December 28, 2004, between Silicon Valley Bank and the Registrant	10-K	10.38	3/31/2005	000-50797
10.41	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				
10.42†	Sublease Agreement, dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant	10-Q	10.9	11/12/2004	000-50797
10.43	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
10.44	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
10.45	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
10.46	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
10.47	Purchase Agreement, dated October 31, 2007, between Alnylam Pharmaceuticals, Inc. and the Registrant	10-Q	10.2	11/8/2007	000-50797

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
	Material Contracts—Stock Purchase Agreement				
10.48	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				
10.49	Asset Purchase Agreement dated as of April 20, 2007 by and among Parivid, LLC and the Registrant	10-Q	10.3	5/10/2007	000-50797
	Additional Exhibits				
*21	List of Subsidiaries				
*23.1	Consent of Independent Registered Public Accounting Firm				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 or 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				

* 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.