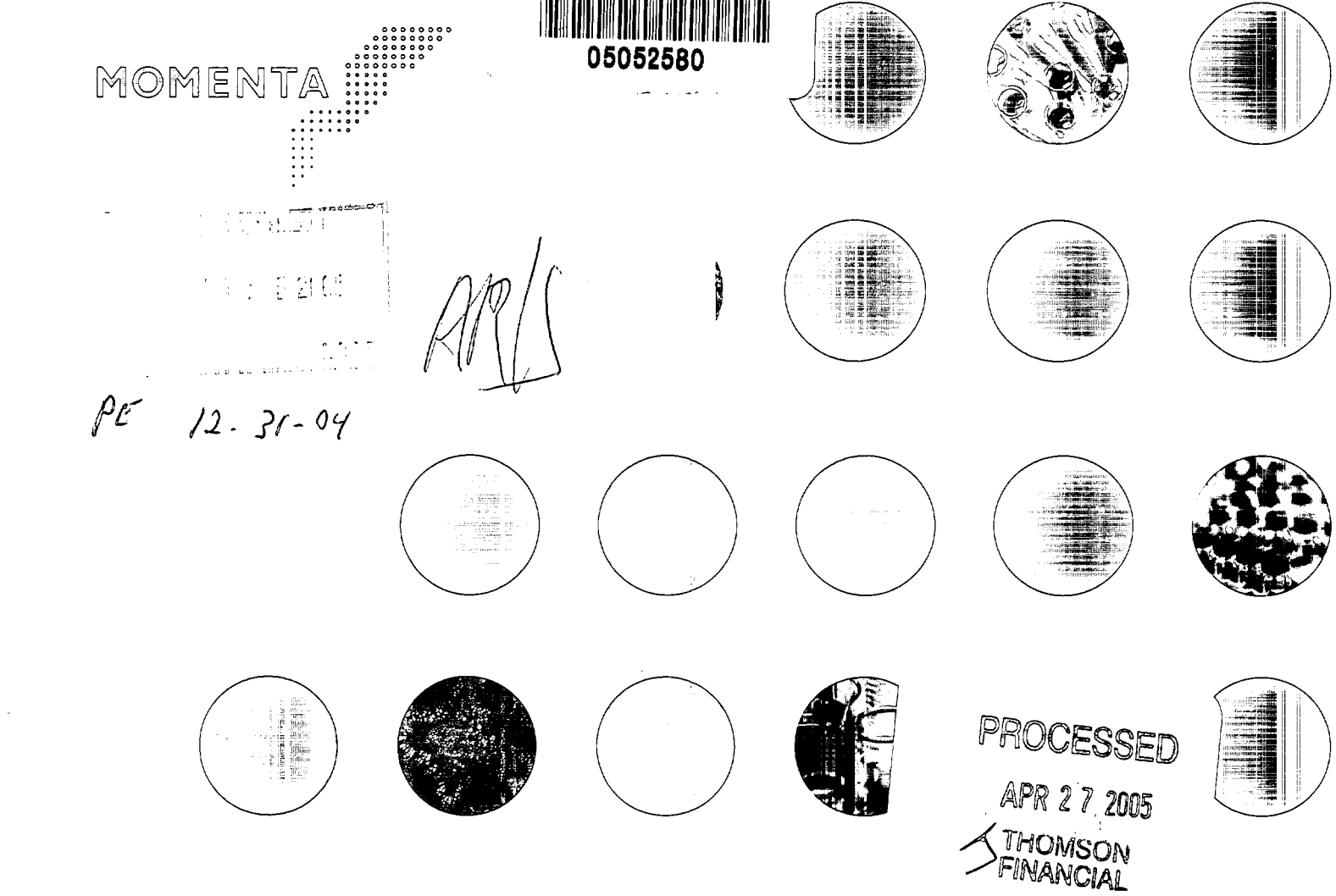
MOMENTA



Momenta is applying scientific breakthroughs in the analysis and engineering of complex sugars to the discovery, development and commercialization of therapeutic drugs.

2004 ANNUAL REPORT

MARKET OPPORTUNITY

$3 billion
Estimated market for heparin drugs

$20 billion
Sales of 10 top glycosylated proteins

Up to 50%
of protein mass can be composed of sugar

$60 billion
Estimated therapeutic protein market by 2010

100%
of cells are coated with sugars

Momenta characterization can detect sugars present at **0.1%**

$81 million
raised in public and private financing

Over 100
patents and applications

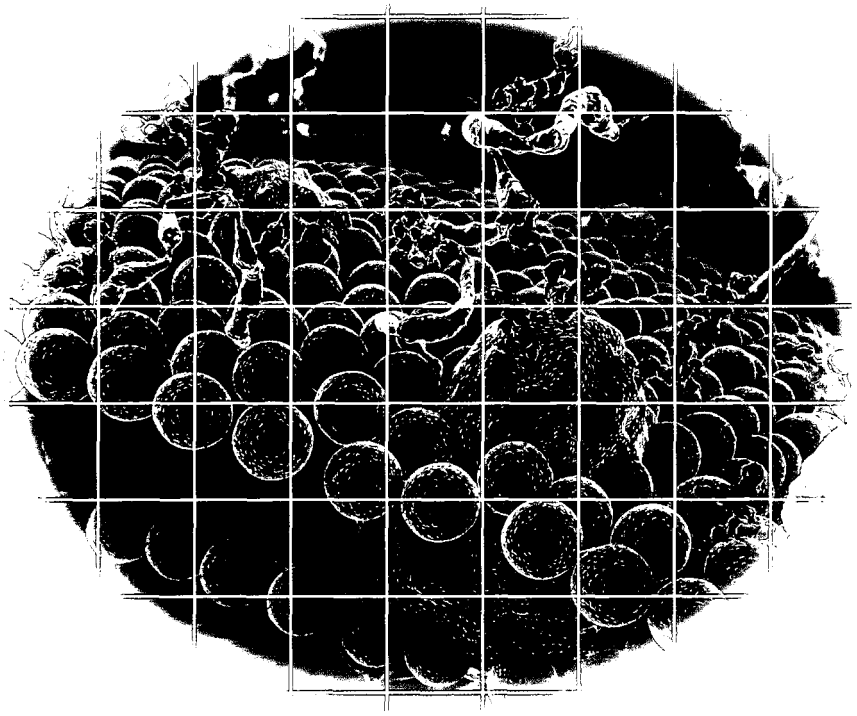
SUGARS: SWEET OPPORTUNITIES

Sugars are one of the least understood or appreciated biomolecules in the human body. Sugars are found in abundance throughout the body, but understanding their structure and role in biology remains a challenge. Where others see a challenge, we see an opportunity.

While great medical advances have come as a result of the sequencing of DNA and proteins, progress in developing a deeper understanding of complex sugars has been comparatively slow. Due to their structural complexity, sugars are much more difficult to characterize, or sequence into their components, than DNA or proteins. As a result, there have been few breakthroughs in the study of sugars – until now.

Momenta Pharmaceuticals has developed a comprehensive, proprietary technology that thoroughly characterizes complex sugars. This technology enables Momenta to elucidate the roles that complex sugars play in fundamental biological processes and in pathways of disease. More importantly, this technology holds great promise for the development of sugar-based therapeutics, an area of drug development that has not been fully exploited to date.

Momenta is building a top-tier biotechnology company based on undisputed leadership in the application of sugars to breakthrough therapeutics. Our goal is to leverage our superior analytic capabilities for characterizing complex sugars to produce novel, improved, and generic drugs aimed at addressing unmet needs across a range of critical diseases, and in turn revolutionize medicine by unlocking the science of sugars.



SUGARS: FUNDAMENTAL TO HUMAN BIOLOGY

Sugars are extremely diverse. They can range from the simple sucrose found in table sugar, to the complex sugars, or carbohydrates, found on and between virtually every cell and protein in the human body. Some sugars are relatively simple homogeneous structures; however, most complex sugars exist as heterogeneous mixtures or three dimensional branched structures attached to other biomolecules such as proteins.

Science has only begun to appreciate the profound role that sugars play in human biology. For example, some complex sugars in the body act in concert with proteins to regulate cell growth, death and the definition of a cell. Other sugars play a critical communication role as they serve as the "interface," modulating signals between cells and their surrounding environment. Depending on the type of sugar and its location, each has a specific responsibility in human biology.

What we understand now is clear – sugars are an essential part of our biologic makeup, just like genes or proteins. The human system can be thought of as an elegant and refined programmatic system:

- Genes provide a master blueprint or template that encodes information;
- Proteins implement this template by turning "on or off" specific biological responses; and
- Sugars serve a critical modulating function, acting as the "dimmer switches" that dictate the magnitude of biological responses.

Defects in how cells manufacture complex sugars and errors in sugar structures interfere with the normal functionality of sugars and are increasingly linked to major diseases including cancer, Alzheimer's disease, viral infections and cardiovascular disease.

CRACKING THE CODE OF COMPLEX SUGARS

The key challenge to realizing the potential of complex sugars has been unlocking their structural complexity. To put this challenge in perspective, DNA can be combined to produce 256 possible four-unit combinations, while the building blocks of proteins can be combined in 160,000 potential four-unit arrangements. Complex sugars, in contrast, may contain as many as 5.3 million four-unit combinations. Prior to Momenta, scientists did not know the structures of most complex sugars, as conventional analytical techniques could not adequately decipher the chemical identity or measure the relative amounts of specific structures in a sugar sequence. The complexity of sugars has simply overwhelmed traditional analytical techniques.

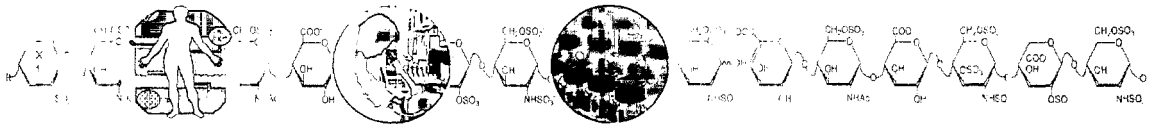
Momenta has developed novel breakthrough technology that now makes it possible to thoroughly sequence complex sugars. Momenta's proprietary approach permits us to analyze sugar structures, correlate structures to biological activities, and re-engineer sugars to create drugs possessing specific favorable properties.

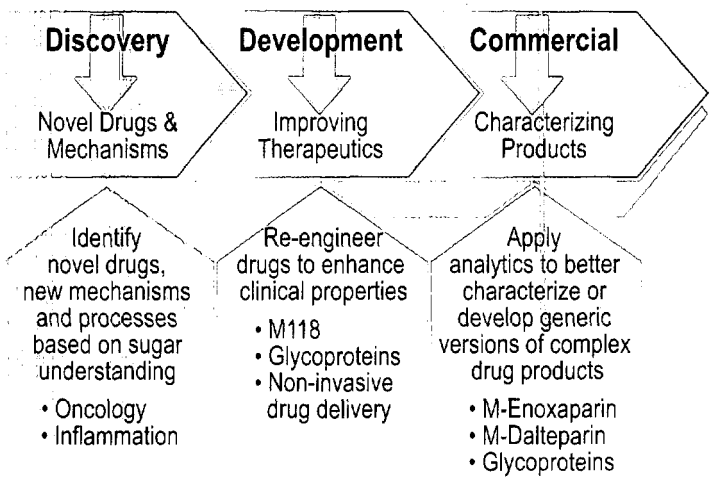
Momenta's technology is comprised of three proprietary elements:

- Novel enzymes that clip sugar chains into smaller pieces;
- Improvements to existing analytic methods for their application to sugars; and
- Mathematical data integration that rapidly solves for a precise structural characterization.

The combination of these techniques provides us with a unique opportunity to capitalize on the role of sugars in cellular function, disease mechanisms and drug action. We believe that with our proprietary capabilities, we have the opportunity to make significant progress in understanding the relationship of complex sugars to human biology and to rationally guide drug development.

SEQUENCING & ENGINEERING OF SUGARS





Momenta's product development strategy is three-pronged:

- Near-term characterization-based opportunities
- Improved versions of existing drugs
- Novel sugar-based compounds and insights into disease biology

Program	Program Objectives	Milestones
M-Enoxaparin	Generic version of Lovenox® LMWH[1,2]	File ANDA in mid-2005
M-Dalteparin	Generic version of Fragmin® LMWH[1]	File ANDA in mid-2006
Glycoprotein	- Better characterized branded products and follow-on generic products - Improved glycoprotein products	Characterize multiple glycoproteins; partnership in 2005
M118	Improved LMWH, rationally engineered to address unmet needs in ACS[3]	File IND in mid-2006
Drug Delivery	Sugar-mediated non-invasive delivery of proteins	Advance development candidates
Oncology	Novel sugar-based anti-cancer compound	Advance discovery candidates

[1]Low molecular weight heparin [2]Partnered with Sandoz, a Novartis company [3]Acute coronary syndromes

PRODUCT OPPORTUNITIES WITH COMPLEX SUGARS: HARNESSING THE POTENTIAL

Momenta's broad technology platform allows us to identify the specific sugar components that contribute to the efficacy and safety of sugar-based products. In addition, we can determine novel biological properties of sugars and use these insights to create new therapeutics. We believe that our technology thus allows us to create generic versions of drugs, improve existing drugs, and design novel drugs with improved efficacy and safety profiles.

Momenta is developing products in multiple areas:

- **Characterizing existing therapeutics.** Momenta is developing generic versions of complex drugs that, without our technology, we believe cannot be duplicated. M-Enoxaparin and M-Dalteparin have the potential to be the only generic versions of the two largest selling LMWHs, which together accounted for over $3 billion in sales in 2004. In addition, we plan to characterize protein-based drugs that contain sugars (glycoproteins). This market opportunity is significant, as sales of the top 10 glycoproteins exceeded $20 billion in 2004.

- **Improving therapeutics by re-engineering the structures of complex sugars.** Complex sugars influence critical properties of drugs, including their efficacy, toxicity and bioavailability. Momenta has the capability to create second-generation versions of drugs containing sugars, such as M118, our reengineered LMWH. We are also exploiting the natural role of sugars in biology in areas like drug delivery.

- **Novel drug discovery using complex sugars.** Momenta's discovery research is focused on understanding the role that sugars play in disease biology. In our oncology program, we are exploring the broader potential of sugars as therapeutic agents, thereby opening up an entire new frontier for drug development.

Our technology enables us to create many innovative therapies with near- and long-term commercial potential that will benefit patients and build value for our shareholders. Our path will have many exciting milestones and accomplishments along the way. We welcome you to join us on this sweet journey.

CORPORATE INFORMATION

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Alan L. Crane
Chairman and
Chief Executive Officer

John E. Bishop, PhD
Vice President, Manufacturing

Steven B. Brugger
Vice President,
Strategic Product Development

Richard P. Shea
Vice President,
Chief Financial Officer

Ganesh Venkataraman, PhD
Co-Founder and
Vice President, Technology

Susan K. Whoriskey, PhD
Vice President,
Business Development

STOCK LISTING

Momenta is traded on the NASDAQ National Market under the symbol MNTA. As of March 14, 2005, there were approximately 72 holders of record of our common stock, which does not include stockholders whose common stock is held in street name.

BOARD OF DIRECTORS

Peter Barrett, PhD
Senior Principal, Atlas Venture

John K. Clarke
Managing General Partner,
Cardinal Partners LP

Alan L. Crane
Momenta Chairman and CEO

Marsha Fanucci
Senior Vice President and CFO,
Millennium Pharmaceuticals, Inc.

Peter Barton Hutt, LLB, LLM
Former Chief Counsel, FDA

Robert S. Langer, Jr., ScD
MIT Professor and
Momenta Co-Founder

Stephen T. Reeders, D.M.
CEO, MVM Life Science Partners

Ram Sasisekharan, PhD
MIT Professor and
Momenta Co-Founder

Bennett M. Shapiro, MD
Former EVP/Head of Research
Merck & Co.

Christoph H. Westphal, MD, PhD
President and CEO,
Sirtris Pharmaceuticals

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Statements contained or incorporated by reference in this Annual Report that are not based on historical facts 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, and projections and the beliefs and assumptions of our management. Forward-looking statements may be identified by the use of forward-looking terminology such as "may," "could," "will," "expect," "estimate," "anticipate," "continue," or similar terms, variations of such terms or the negative of those terms. 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.

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, 2004

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: **None**

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

Common Stock, $.0001 par value
(Title of class)

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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting Common Stock held by non-affiliates of the registrant as of June 30, 2004 was $71,194,976 based on the last reported sale price of the Common Stock on the Nasdaq Stock Market on that date.

Number of shares outstanding of the registrant's Common Stock as of March 15, 2005: 25,483,245.

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 2005 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

TABLE OF CONTENTS

PART I

Item 1. BUSINESS

Overview

Momenta is a biotechnology company specializing in the detailed structural analysis and design of complex sugars for the development of improved versions of existing drugs, the development of novel drugs and the discovery of new biological processes. We are also utilizing our ability to sequence sugars to create technology-enabled generic versions of sugar-based and biologic drug products. Through detailed analysis of the molecular structure of complex sugars, we believe our proprietary technology enables us to define the specific sugar sequences contained in complex sugar-based drugs, including those structures that had previously not been described due to lack of available technology. In addition, we are able to derive a more complete understanding of the roles that sugars play in cellular function, disease and drug action based on our structural and biological analytic capabilities. With our capabilities for understanding complex sugars, we have developed a diversified pipeline of near-term product opportunities and novel discovery and development candidates.

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox®, a low molecular weight heparin, or LMWH, used to prevent and treat deep vein thrombosis, or DVT, and treat acute coronary syndromes, or ACS. Sanofi-Aventis reported worldwide sales of Lovenox to be approximately $2.4 billion in 2004, and analysts project sales to exceed $3.8 billion by 2008. The development of M-Enoxaparin is enabled by our ability to thoroughly analyze sugars. We believe it will be difficult for others to perform similar analyses. We have formed a collaboration with Sandoz N.V., and Sandoz Inc., collectively Sandoz, affiliates of Novartis AG, to jointly develop, manufacture and commercialize M-Enoxaparin. We, in collaboration with Sandoz, plan to file an Abbreviated New Drug Application, or ANDA, for M-Enoxaparin in mid-2005. In addition, we are developing M-Dalteparin, a technology-enabled generic version of the LMWH Fragmin®, and plan to file an ANDA for M-Dalteparin in mid-2006. Currently, there are no FDA-approved generic equivalents of Lovenox or Fragmin.

In early 2005, we announced goals relating to the application of our technology to the analysis of branched sugars on proteins, or glycoproteins. Many of the leading marketed protein therapeutics contain sugars. We believe our technology can be applied to analyze and quantify the specific sugars found on these glycoproteins to enable a better understanding of existing marketed protein drugs and to facilitate the development of equivalent versions of these products. We intend to work with innovator companies to help them understand the sugars contained on their products, to, among other things, assist them with manufacturing and quality control activities. In addition, we believe our technology offers the opportunity to develop follow-on biologics. While the specific type of information that will be required to approve a follow-on glycoprotein drug has not been determined by the FDA, we believe improved capabilities for characterizing, or determining specific sequences of the sugars, will be critical to any future opportunity created for FDA approval of such drugs, and we may apply our technology to the development of follow-on protein products. We also believe our technology can be applied to modify the complex sugars on therapeutic proteins to improve the efficacy, reduce side effects and modify the dosing frequency of selected protein drugs.

Our business strategy is to utilize near-term product opportunities such as M-Enoxaparin, M-Dalteparin, and the application of our analytical capabilities to glycoproteins to provide a funding source for our development and discovery programs. Over the long term, we expect to generate value by leveraging our understanding of sugars to create novel therapeutics which address critical unmet medical needs in a wide range of disease areas including oncology, cardiovascular disease, inflammation and immunology. Currently, our improved and novel drug development programs include M118, which is a LMWH specifically designed for the treatment of ACS; the application of our technology to

improve the non-invasive delivery of therapeutic proteins; and a discovery program focused on oncology.

We are a Delaware corporation. We were incorporated and began operations in 2001 under the name Mimeon, Inc. and changed our name to Momenta Pharmaceuticals, Inc. in September 2002. Our principal 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.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended (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, 450 Fifth Street, NW, 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, (including but not limited to Momenta®) 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.

Background on Sugars

Overview

The ability to sequence DNA and proteins enabled the first biotechnology companies to develop breakthrough products. Recent scientific studies have demonstrated that sugars also play fundamental roles in the regulation of biological activity and, consequently, in the cause and treatment of many diseases as well as in drug action. Sugars, together with DNA and proteins, regulate biological processes and pathways in the human body. The manner in which a cell produces sugars is critical for normal cell function and communication. Importantly, malfunctions in complex sugar production and the resulting abnormalities in sugar structures have been shown to play fundamental roles in numerous major diseases, such as cancer, cardiovascular disease, Alzheimer's disease, inflammatory disease and viral infection.

Due to the structural complexity of sugars and the lack of sophisticated analytical tools and methods to examine the minute quantities of sugars that occur in nature, sugars have not been well defined nor have their molecular structures been determined. Structurally, complex sugars are composed of individual saccharide building blocks, or monosaccharides, that may form linear or branched chains. Without being able to identify specific structures, it has been difficult to monitor how sugars act in biological organisms. In addition, we believe it has not been possible to characterize, or sequence, drugs which are complex mixtures containing sugars. As a consequence, the development of drugs containing sugars to date has been through more of a "trial-and-error" approach. We believe

understanding the structure, specific function and manner in which complex sugars affect specific drugs as well as critical biological processes and pathways will provide significant commercial opportunities for drug development.

Applications of Complex Sugars to Drug Development

Understanding the role that sugars play in the body, as well as their role in selected therapeutics, creates opportunities for complex sugar-based drug discovery and development. In general, there are four major ways in which the knowledge of complex sugars can be applied to drug development:

Complex sugar-based therapeutics

Complex sugars can be used as therapeutic drugs. One prominent example is the heparin class of drugs, which are heterogeneous mixtures of complex sugar chains extracted primarily from the lining of pig intestines. Heparins are used therapeutically to prevent blood clotting and represented approximately a $3 billion market in 2004. Other complex sugar-based drugs in development include chondroitins for neural injury and pectins for cancer.

Complex sugars on therapeutics

There are three major drug classes that frequently contain complex sugars: proteins (including antibodies); vaccines and antibiotics. Therapeutic proteins, the vast majority of which contain sugar coats, are an increasingly significant segment of the pharmaceutical market as worldwide annual sales of therapeutic proteins are projected to exceed approximately $60 billion by 2010. Altering the complex sugar coat of a protein can dramatically change its properties. The sugar coat influences how long the protein remains in the body, the stability, activity, and safety of the protein, as well as the way in which the immune system responds to the protein, or immunogenicity.

Complex sugars in small molecule and antibody development

The fields of genomics and proteomics have identified large numbers of genes and proteins. Understanding only DNA and proteins, however, provides incomplete information about the biological function of potential drug targets. Identifying appropriate drug targets also depends on understanding the sequential interaction of proteins in disease, known as disease pathways. We believe deciphering the role of sugars, which can both activate and regulate these pathways, provides a more complete picture of biology and may lead to critical new insights for drug discovery.

Complex sugars as diagnostic and prognostic measures of disease

Complex sugar patterns on proteins and cells can be used to diagnose disease, and we believe can enable a more accurate determination of the stage of disease and improve disease management. Diseases, such as cancer or inflammation, cause fundamental changes in affected cells, which in turn cause changes in complex sugar structures. These changes in sugars are often detectible earlier in the disease process than are elevations in protein levels caused by disease, which have been previously used as markers for disease detection. By detecting changes in the sugar patterns, it may be possible to more accurately diagnose disease and determine disease severity with greater sensitivity than conventional protein-based markers.

Challenges Associated with Analyzing Sugars and Momenta's Technology Solution

A number of challenges have inhibited the widespread analysis and application of complex sugars to drug development, including the structural complexity contained in sugars, the inability to duplicate sugars in large quantities for analysis, and the inherent heterogeneity found in sugars. Complex sugars have far more information density than DNA and proteins primarily due to the greater number of

distinct building blocks contained in sugars. In addition, while DNA and proteins exist only in linear forms, sugars can also exist in branched forms, adding further structural complexity and information density.

DNA and proteins can be isolated and amplified and, therefore, studied in pure or homogeneous forms, permitting straightforward analysis. In contrast, most complex sugars exist as heterogeneous mixtures of sugar chains. Current technologies are unable to adequately separate mixtures of sugar chains into individual sugar chains and sequence specific chains or individual saccharide building blocks.

Momenta has developed an integrated technology solution that we believe addresses the challenges of creating drugs based on complex sugars. Our technology enables rapid, precise and comprehensive sequencing of complex sugars. Using a comprehensive library of proprietary enzymes or reagents, we break down sugar chains, including those contained in complex mixtures, into measurable units. By applying these enzymes and reagents to complex sugar sequences or mixtures, we gain specific knowledge about the basic saccharide units, which make up longer sugar chains, as well as the sequence order of the units. We then 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, in order to analyze and gather information regarding the components, structure and arrangement of the building blocks in the sugar chains. The third component of our technology is the application of proprietary mathematical methods that integrate the disparate information obtained from various analytic techniques to arrive at a specific, numerically derived solution describing the complete structure of a specific sugar sequence. The combined sensitivity of all of our analytical techniques allows us to work with very small quantities of material. Our proprietary technology has enabled us to rapidly sequence and accurately verify complex sugars in a matter of minutes to hours.

Momenta Product Pipeline

Our product pipeline consists of technology-enabled generic versions of marketed sugar-based drugs, improved versions of existing products and novel discovery candidates. Our product development goals in these areas are summarized below:

Develop technology-enabled generic versions of complex drugs through characterization

Many currently marketed drugs containing sugars have not been fully characterized due to a lack of available technology. These drugs include heparins, therapeutic proteins, antibodies, vaccines and antibiotics. Our technology allows us to determine the precise sugar sequences contained in marketed, complex drugs containing sugars, including those structures that had not previously been described. The inability to analyze existing complex sugar structures found in drugs has made it difficult to obtain approval of generic versions of such drugs to date. We believe that the information obtained from our analysis can be applied to develop technology-enabled generic versions of complex marketed products that are either sugar-based or contain sugars.

Improve therapeutic products

We are creating proprietary drugs that represent improvements over currently marketed drugs by:

- *Rationally designing complex sugar structures.* We are utilizing our technology to rationally engineer heparin and protein drugs which contain sugars to improve their properties and address unmet medical needs. For example, our development candidate, M118, is a LMWH that has been engineered to possess an improved therapeutic profile to treat patients diagnosed with ACS.

- *Utilizing drug delivery technologies.* Most therapeutic proteins, as well as other large macromolecules, can only be introduced into the body through injection. We have discovered that sugars can efficiently transport these drugs across mucosal membranes, such as in the lungs and gastrointestinal tract. We believe our technology will enable improved delivery of a broad range of therapeutic protein drugs, leading to increased bioavailability, or the quantity and duration of time a drug is present in the bloodstream, improved safety and the ability to deliver larger drugs. We are currently applying this technology to develop pulmonary formulations of several marketed therapeutic proteins.

Discover novel drugs

We are applying our understanding of the role sugars play in basic biology and in disease onset, progression and treatment to develop novel, sugar-based, small molecule and antibody drugs. Our drug discovery program in oncology is based on our *in vitro* and *in vivo* research that has shown that sugars can both decrease the growth and increase the death of cancer cells.

The specific products and technology applications in our pipeline are summarized in the table below:

Drug Candidate(s)	Therapeutic Area	Current Stage of Development
M-Enoxaparin*	Thrombosis	ANDA mid-2005
M-Dalteparin	Thrombosis	ANDA mid-2006
Glycoproteins	Various	Discovery / Preclinical
M118	Cardiovascular Disease	Preclinical
Pulmonary Delivery of Proteins	Various	Preclinical
Sugar Therapeutic	Oncology	Discovery

* In collaboration with Sandoz

Near-Term Product Opportunities

M-Enoxaparin

Our most advanced product candidate, M-Enoxaparin, which is enabled by our technology and understanding of complex sugars, is designed to be a generic version of Lovenox. Lovenox is a widely-prescribed LMWH used for the prevention and treatment of DVT and treatment of ACS. Lovenox is distributed worldwide by Sanofi-Aventis and is also known outside the United States as Clexane® and Klexane®. Sanofi-Aventis reported worldwide sales of Lovenox of approximately $2.4 billion in 2004, with approximately $1.5 billion coming from the United States market. Analysts project that Lovenox will remain a leading LMWH product, growing to over $3.8 billion in annual sales by 2008.

Sanofi-Aventis, in a Citizen Petition filed with the FDA in February 2003, requested, among other things, that the FDA refrain from approving any ANDA for a generic version of Lovenox until such time as Lovenox has been fully characterized. Sanofi-Aventis has reiterated this request and provided additional commentary and supporting data directed at the need for full characterization of Lovenox in subsequent Citizen Petition supplements. Our ability to sequence and analyze complex mixtures of sugars has allowed us to analyze Lovenox and develop a process that we believe can be used to make a generic version of Lovenox that will meet the FDA requirements for ANDA approval. We believe it will be difficult for others to perform similar analyses. We have formed a collaboration with Sandoz to jointly develop, manufacture and commercialize M-Enoxaparin. We anticipate filing an ANDA for M-Enoxaparin in mid-2005.

Lovenox composition

Lovenox is a heterogeneous mixture of complex sugar chains that, in our view, has not been adequately analyzed to date. It is comprised of sugar chains that vary with respect to length and sequence, resulting in a diversity of chemical structures in the mixture. The current description 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. Molecular weight distribution provides a rough measure of the range of chain lengths but provides no information about detailed sequences or chemical structures contained in Lovenox. The *in vitro* measures of anti-Xa and anti-IIa activity describe certain aspects of anticoagulation but only partially 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.

The need for detailed analysis of enoxaparin

According to FDA regulations, a generic drug must have, among other requirements, the same active ingredients as the innovator or the "reference listed drug product" upon which the generic application is based. The FDA's definition of an active ingredient is, "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals."

Through the application of our technology, we believe that we will meet FDA requirements and, therefore, have our regulatory application for M-Enoxaparin approved. Under FDA guidelines, generic drugs are considered pharmaceutically equivalent to their branded counterparts if, among other things, they contain the same active ingredient(s), dosage form, route of administration and are identical in strength or concentration. To be therapeutically equivalent, a generic product must first be pharmaceutically equivalent and also be expected to have the same clinical effect and safety profile, thus making it typically interchangeable with the branded product; interchangeable products are denoted by an "A" rating by the FDA. Products with "A" ratings are generally substituted for the innovator drug by both in-hospital and retail pharmacies and many health insurance plans require automatic substitution of "A" rated generic versions when they are available, although physicians may still prescribe the branded drug for individual patients.

Legal matters

Sanofi-Aventis has one listed patent for Lovenox in the Orange Book, the FDA's listing of approved drug products. According to Sanofi-Aventis, U.S. Patent No. 5,389,618, or the '618 patent, expires February 14, 2012. In June 2003, Sanofi-Aventis announced that it received individual notices from Amphastar Pharmaceuticals, Inc., or Amphastar, and Teva Pharmaceuticals USA, Inc., or Teva, indicating that each had filed with the FDA its own ANDA for enoxaparin. According to Sanofi-Aventis, each ANDA included a paragraph IV certification, or a patent certification stating that the '618 patent was either not infringed, was unenforceable or invalid. Amphastar and Teva included the patent certification because they were seeking from the FDA authorization to manufacture and market a generic version of Lovenox in the United States prior to the expiration of the '618 patent. Submitting such certifications allowed Sanofi-Aventis to sue Amphastar and Teva for patent infringement of the '618 patent in August 2003, even though Amphastar and Teva have not marketed their generic versions of Lovenox. Amphastar and Teva have asserted non-infringement, invalidity and/or unenforceability of the '618 patent. They have also sought related declaratory judgment relief against Sanofi-Aventis. A trial date between Sanofi-Aventis and Amphastar and Teva, whose cases have been consolidated, has been set for September 2005. Amphastar has filed three motions for summary judgment, requesting that the court rule that the claims of the '618 patent are invalid and/or unenforceable. Sanofi-Aventis has opposed Amphastar's motions. The court has not yet ruled on either of Amphastar's motions. Neither Teva nor Amphastar are currently marketing a generic version of enoxaparin, nor can they

market such product prior to expiration of the '618 patent unless the court concludes that the patent is invalid or not infringed, and the FDA approves Amphastar's and Teva's respective ANDA filings.

In May 2003, Sanofi-Aventis filed a reissue application for the '618 patent in the United States Patent and Trademark Office ("USPTO"). As part of the reissue process, the inventor of the '618 patent declared it was partly inoperative because of a defective specification. On December 20, 2004, Sanofi-Aventis announced that the USPTO had allowed the reissue application to issue as a patent. To date, the reissue application has not yet been issued as a patent; however, we anticipate it will issue.

We continue exploring our legal options to obtain approval to market our generic version of Lovenox prior to expiration of the '618 patent. We expect Sanofi-Aventis to bring suit for patent infringement of the '618 patent against us should we decide to include a paragraph IV certification with our ANDA and thus attempt to commercialize M-Enoxaparin before expiration of that patent. Sanofi-Aventis may assert other patents, such as, for example, the reissue patent from which the '618 patent is based. With certain exceptions, Sandoz will indemnify us for any losses we incur or must pay to a third party which result from patent infringement litigation by Sanofi-Aventis, and certain other claims, in each case which relate to the development and commercialization of our generic version of Lovenox. Sandoz may offset certain of these costs against the profit-sharing amounts, the royalties and the milestone payments they may be required to make to us.

M-Dalteparin

We intend to develop M-Dalteparin, a technology-enabled generic version of Fragmin (dalteparin), the second largest selling LMWH product in the United States, and to submit an ANDA by the middle of 2006. Fragmin is currently marketed by Pfizer in the United States and Europe and by Kissei Pharmaceutical Co, Ltd. in Japan. The product is indicated for the prevention of DVT and selected indications in ACS. The Orange Book patent listed for Fragmin expired in January 2005.

Similar to Lovenox, Fragmin is currently described by molecular weight distribution, anti-Xa activity and anti-IIa activity. We believe that additional analysis is necessary to demonstrate that a generic version of Fragmin has the same active ingredients as the branded drug, and that it will be difficult for others to perform this analysis. Through our technology, we believe we have the ability to analyze Fragmin and demonstrate that our generic product has the same active ingredients as Fragmin, thereby enabling the FDA to approve the ANDA.

We plan to leverage the same technical, regulatory and commercial strategy that we are currently employing with M-Enoxaparin to successfully commercialize M-Dalteparin. We believe limited technical effort and costs will be required to successfully analyze Fragmin and develop an approvable technology-enabled generic product that could be considered by the FDA to be interchangeable with Fragmin.

Glycoproteins

Over the next few years, many existing therapeutic protein drugs containing sugars, or glycoproteins, which were approved as Biologic Licensing Applications, or BLAs, will lose patent and marketing exclusivity protection. Therapeutic proteins represent a significant share of the pharmaceutical market. In 2003, worldwide sales of therapeutic protein products, or biologics, totaled more than $33 billion. Analysts estimate that by 2010, sales of biologic products will exceed approximately $60 billion as biologics comprise a significant percentage of drugs currently in development. Most of these products are glycosylated, or contain sugars on the exterior of their protein compositions. Nine of the top ten selling protein products in 2004 were glycosylated.

We believe that there are multiple near-term product opportunities that can be achieved by applying our technology to identify the mixtures of specific sugar structures found on proteins and in many cases, correlate these structures to biological function. Unlike small molecule drugs, therapeutic

proteins are considered to be more complex as they are manufactured by processes that utilize cells obtained from biological organisms. These manufacturing processes yield products with a greater degree of heterogeneity and complexity than small molecule drugs, which are typically produced by a well-defined chemical synthesis. To date, it has been impossible to determine the specific sugar structures contained on glycoproteins due to lack of available technology. New approaches are therefore required to analyze these products.

We plan to apply our technology to the analysis of glycoproteins in several ways:

- *Characterization of Biologics.* We intend to work with innovator biotechnology companies to help them better understand the sugars contained in their products, which can assist them with manufacturing and quality control activities.
- *Improved Biologics.* We believe we can assist biotechnology companies in developing improved and next generation versions of biologic products by analyzing and modifying specific branched sugar structures found on glycoproteins. Sugars on therapeutic proteins affect, among other things, the half-life, the specificity of targeting, as well as the ability of the protein to transmit signals across cells. For example, modification of the sugars contained in Amgen's therapeutic protein, erythropoietin, lengthened the amount of time that the product is active in the human body and enabled the creation of the second generation drug, Aranesp®, with a decreased frequency of dosing.
- *Follow-on Biologics.* We believe recent advances in analytic technology, such as the technology developed by us, will likely play a significant role in facilitating the development of equivalent versions of biologics. The market for follow-on or generic versions of biologics, given projected patent expirations, is estimated to reach approximately $12 billion by 2010. Increased capabilities for characterizing or comprehensively analyzing the sugars which exist on most therapeutic proteins are likely to be critical for meeting standards for approval of follow-on biologics. We may, therefore, seek to apply our technology to create technology-enabled generic versions of marketed biologic products, leveraging strategies similar to those of M-Enoxaparin.

The need for detailed analysis of glycosylated proteins

The FDA and industry representatives are actively engaged in a scientific dialogue to determine the need for characterization and the technology required for identifying and replicating the active ingredients contained within protein products in order to establish a pathway for the approval of follow-on protein products. Central to the debate is whether current technologies are available to characterize the sugars on glycoproteins and to determine the effect that glycosylation has on protein products' safety and efficacy. It has long been recognized that proteins containing variations in sugar patterns possess varied biological attributes. We believe that the branched sugar patterns contained in glycoprotein products contribute to the overall safety and efficacy profile of the drug, and affect the half-life, product stability and immunogenicity, among other properties. Therefore, sugars must be considered as active ingredients in any characterization of the protein product.

Most therapeutic protein drugs and biologics were approved by the FDA under the Public Health Services Acts as BLAs. There is currently no FDA-sanctioned pathway to enable approval for generic or follow-on versions of therapeutic protein and biologic products licensed under the Public Health Services Act. Even for follow-on versions of therapeutic proteins approved through New Drug Applications, or NDAs, the legal and scientific aspects of route to market are intensely debated. It is anticipated that the U.S. Congress, based upon guidance from the FDA, will establish a regulatory path for approval of generic versions of therapeutic protein products and biologics approved under the Public Health Service Act sometime in the future.

Momenta technology for analyzing and engineering glycosylated proteins

We believe that our technology can be applied to analyze the sugars contained in glycosylated proteins and provide distinct insight into the role that sugars play in the proteins' overall safety and efficacy profiles. Determining the structure of branched sugars found on proteins has many of the same analytic challenges as determining the structure of linear sugars. We believe that the development of analytic technologies for branched sugars, analogous to those we have developed for analyzing linear sugars, can overcome many of these challenges. Further, our engineering and analytical capabilities can be applied to develop new forms of sugars and to determine how manufacturing processes change the distribution of sugars present on a protein, thereby changing its biological properties.

In early 2005, we announced our intention to characterize multiple glycosylated therapeutic protein products. We are engaged in discussions with companies, including innovator companies, working on developing improved or similar versions of therapeutic proteins, with the goal of establishing a glycoprotein product collaboration in 2005.

Additional Development Products

M118

M118 is a LMWH that we rationally designed to provide improved anti-clotting activity and flexible administration to treat patients with ACS. Currently marketed LMWHs primarily inhibit a single factor that contributes to clot formation, whereas M118 is a potent inhibitor of multiple factors in the blood that lead to clot formation. This is critical in ACS patients who have an existing clot in a coronary artery because of the need to prevent not only formation of new clots, but also the extension of existing clots. Heparins, including unfractionated heparin, or UFH, and LMWHs, are routinely used as baseline therapy in ACS, and if required, in subsequent invasive procedures such as angioplasty and coronary artery bypass graft surgery, or CABG. The selection of a particular heparin is dictated by the drug's efficacy, predictability, safety and the ability to monitor the level of and reverse anticoagulation. Due to M118's beneficial biological activities and its flexibility to be used in patients regardless of the specific treatment required, we believe M118 could become the baseline heparin of choice to treat patients diagnosed with ACS, including those patients who subsequently require angioplasty or CABG.

Market overview

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. While most patients are initially medically managed with anti-clotting agents such as UFH or LMWH, patients who do not respond well to the treatment will typically require angioplasty or CABG. Both angioplasty and CABG require anticoagulant therapy to prevent clot formation during the procedure. UFH is currently the foundation anti-clotting agent used in both angioplasty and CABG. No LMWHs are currently approved for use in either angioplasty or CABG. M118 is designed to be a LMWH that could be used in multiple settings, including initial medical management, angioplasty or CABG.

M118 development strategy

To design M118, we utilized our proprietary analytical methods and enzymes, together with our ability to sequence the complex sugar chains within UFH starting material, to identify the activity of various sugar sequences. We then tailored the design of M118 to develop a drug candidate with specific attributes to address the unmet medical needs of anticoagulation therapy in ACS, including, among others, reversibility and the ability to be monitored. Our preclinical animal studies have demonstrated potential benefits of M118 over UFH and other LMWHs. These potential benefits include:

- *Increased efficacy.* In direct comparison with UFH and other LMWHs, M118 more effectively prevented clotting of injured arteries in a rat model. We have demonstrated through *in vivo* and *in vitro* experiments that M118 acts at multiple points in the coagulation cascade by inhibiting factor Xa and factor IIa and through the release of tissue factor pathway inhibitor.
- *Reversibility.* We have demonstrated in animals that the anti-clotting effects of M118 are fully reversible by administering protamine sulfate, the standard drug used to reverse anticoagulant activity. LMWHs are not fully reversible with protamine.
- *Ability to monitor.* Due to the presence of certain saccharide sequences in M118, the anti-clotting activity of M118 can be monitored by standard laboratory tests that detect the presence of factor IIa, or thrombin. Currently, LMWHs cannot be monitored efficiently with routine laboratory tests.
- *Diminished adverse reaction risk.* M118 has been engineered to reduce certain sugar sequences contained within UFH and other LMWHs that may provoke a potentially life-threatening reaction known as heparin-induced thrombocytopenia, or HIT.

We are working with third-party manufacturers to produce the drug substance required for M118. In November 2004, we made a strategic decision to pursue development of an alternate manufacturing process for M118. This process development effort was intended to yield a more efficient and reproducible process for manufacturing the drug substance. We announced that the development of the alternate manufacturing process may result in a six to twelve month delay in the filing of the investigational new drug application, or IND, for M118, revising our target IND filing date to mid 2006. Assuming our preclinical testing is successful and we do not encounter other difficulties, we will begin Phase I clinical trials shortly thereafter. We plan to develop M118 through Phase IIa clinical trials and then seek a profit-sharing arrangement with a collaborator that includes co-development and co-promotion rights.

M118 is currently in preclinical development and we have not yet demonstrated statistically significant differences in our animal experiments due to the small number of animals treated. In addition, results from early animal tests also are not always duplicated when product candidates are tested in humans.

Sugar-Mediated Non-Invasive Delivery

Through our sequencing capabilities, we have identified a mechanism by which sugars facilitate the transport of drugs across mucosal membranes, leading to high levels of bioavailability. These sugars can be mixed with a variety of drugs enabling their delivery across mucosal membranes into the bloodstream. Our technology targets the many mucosal membranes present in the body, including those membranes in the lungs, nasal passages and gastrointestinal tract. As a result, we believe our technology may enable the pulmonary, nasal or oral delivery of both small and large molecule drugs currently administered by injection.

Our current focus is on pulmonary delivery of therapeutic proteins, where bioavailability has been a challenge. We have performed initial proof-of-concept, preclinical safety, efficacy and bioavailability studies to test the delivery of insulin and human growth hormone through the lung. In our studies, we have been able to achieve five to ten times greater bioavailability compared with other published advanced technologies in comparable animal studies. Preliminary data has suggested no adverse findings. We believe our pulmonary delivery of therapeutic proteins has distinct advantages over current technologies. Some of these advantages include delivery of larger therapeutics proteins, the use of natural sugar formulations and higher bioavailability.

We continue to develop our pulmonary formulation of insulin as a proof-of-concept for our pulmonary delivery platform. We also continue to improve the engineering of the sugars which facilitate delivery as well as add to our understanding of the mechanism of action of these sugars. Our primary product development opportunities are focused on pulmonary delivery of therapeutic proteins such as human growth hormone, erythropoietin, and interferon beta, where pulmonary development efforts by others have not been particularly successful. We are currently exploring co-development opportunities for our pulmonary delivery candidates which are in the preclinical phase.

Discovery Product Candidates

Drug discovery efforts to date have generally ignored the role that complex sugars play in modulating biological systems. Recent research has shown that sugars play a critical role in influencing protein signaling to fundamentally affect basic biology. We believe understanding the role of sugars in disease progression can be used to discover novel therapeutics for a range of diseases as well as to discover new disease mechanisms that can be targeted with small molecule or antibody drugs. We also believe it will be possible to develop sugar-based drugs to modulate these pathways.

Our initial area of focus is in oncology. Cancer is a disease characterized by unregulated cell growth. Complex sugars are involved in the conversion of normal cells into cancerous cells, the regulation of tumor growth and also play a role in tumor invasion and metastasis. As normal cells change into cancerous cells, the sugar coats which are found on cell surfaces change as part of tumor progression. Detection of these changes potentially provides a new, sensitive means to detect cancer. In addition, since sugars play a role in tumor growth and metastasis, the introduction of sugar structures that can prevent these processes provides a potential avenue for development of new therapeutics. We have shown through *in vitro* and *in vivo* studies that sugars selectively inhibit proliferation of cancer cells and increase apoptosis, or cell death.

Sugar-based drugs

We have identified sugar sequences that have demonstrated potent anti-tumor effects in animals, as compared with control groups. These sugar sequences were capable of both inhibiting tumor growth and preventing metastasis. These anti-cancer activities were obtained at microgram per kilogram doses, one thousand fold below the projected clinical dose, demonstrating the high potency of these compounds, though these early preclinical studies did not include adequate numbers of animals to demonstrate statistical significance.

Sugar-based diagnostics

Prostate specific antigen, or PSA, is a protein expressed by the prostate in human males. When males develop cancer of the prostate, the level of PSA expressed in the blood increases. We have determined that there are distinctive changes that occur in the sugars that are bound to the PSA protein that can better discriminate between cancerous and non-cancerous states. We believe our technology could be used to develop an improved diagnostic for prostate cancer.

Collaboration and Licenses

Sandoz

In November 2003, we entered into a collaboration and license agreement with Sandoz to jointly develop and commercialize injectable enoxaparin and any improved injectable form of enoxaparin for which Lovenox is the reference listed drug and for which an ANDA could be approved by the FDA. Under the terms of this agreement, 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.

We are in discussions with Sandoz regarding an exclusive license to develop and commercialize injectable enoxaparin outside of the United States. Further, Sandoz may exercise a right of first negotiation to work with us on the research, development, manufacturing or commercialization, inside and/or outside the United States, of a generic version of Fragmin, M118, and/or enoxaparin administered by any route of delivery other than injection or certain improved forms of enoxaparin for which approval by the FDA would require the filing of a NDA.

Under this collaboration, Sandoz makes certain payments to us. As mutually agreed, we provide, and Sandoz pays us for full-time equivalent 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, share profits with us. Alternatively, in certain circumstances, if there are third party competitors marketing a Lovenox-Equivalent Product, Sandoz will pay royalties to us on net sales of injectable enoxaparin. If certain milestones are achieved with respect to injectable enoxaparin under certain circumstances, Sandoz may also make certain milestone payments to us, which would reach $55.0 million if all such milestones are achieved. If the development expenses and certain legal expenses, in the aggregate, exceed a specified amount, Sandoz is permitted to offset a portion of the excess 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 us 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 the injectable enoxaparin product prior to receipt of final legal clearance from any such infringement claims, as well as determine the price at which it will sell the injectable enoxaparin product. Sandoz is also responsible for the filing of the ANDA for 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. In addition, 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.

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 further amended in 2003 and 2004. 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. 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 (i) methods and technologies for characterizing sugars, (ii) certain heparins, heparinases and other enzymes, and (iii) synthesis methods.

Subject to typical retained rights of M.I.T. and the United States government, we are granted: various exclusive and nonexclusive rights to certain methods and technologies, heparinases and other enzymes for the purpose of characterizing sugars, manufacturing products, and selling or leasing sequencing machines; exclusive rights to certain novel heparins and heparinases, including M118, for use as therapeutics; and nonexclusive rights to certain methods and technologies for the synthesis of sugars for use as therapeutics.

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 our failure 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 maintenance fees. The Company recorded $117,500, $57,500 and $90,000 as research and development expenses related to M.I.T. license and maintenance fees pursuant to these agreements in the years ended December 31, 2004, 2003 and 2002 respectively. Starting in 2005, we are

required to pay annual license maintenance fees pursuant to these agreements ranging, in the aggregate, from $82,500 to $157,500. In addition, during 2001 and 2002, in exchange for the licenses granted under the amended and restated license agreement, M.I.T. was issued 293,136 shares of our common stock valued at $0.3 million and certain employees of M.I.T. who are inventors of the licensed patents and patent applications were issued an aggregate of 81,852 shares of our common stock valued at $0.1 million. 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 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 which issue and are licensed to us by M.I.T. under such agreement. The issued patents include 12 United States patents that expire between 2012 and 2022, and 17 foreign patents that expire between 2012 and 2013. We expect that additional patents will issue from filed 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 or both agreements 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 or both agreements 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 have 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 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.

The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory

In November 2002, we entered into an agreement with The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory, or Lawrence Berkeley National Lab, under which we exclusively licensed certain patents and patent applications covering the metabolic synthesis of sugars and glycoconjugates. This agreement was subsequently amended in 2004 and 2005. Subject to typical retained rights of Lawrence Berkeley National Lab and the United States government, we were initially granted an exclusive license, with the right to grant sublicenses, for the synthesis, production or modification of sugars and glycoconjugates in or on biological molecules for purposes of researching, developing and commercializing products, services and processes for all human therapeutic applications, excluding the sale of research reagents. During 2005 we elected to retain the license under this broad field. Upon our request, but subject to statutory restrictions or obligations to research sponsors, Lawrence Berkeley National Lab must disclose certain information that is necessary or useful for our use of the licensed patent rights and we have a non-exclusive, royalty-free right to use such information.

Lawrence Berkeley National Lab has an obligation to notify us of certain future inventions that are available for licensing by Lawrence Berkeley National Lab prior to entering into negotiations with

others. However, Lawrence Berkeley National Lab is not required to license those inventions to us, or even to negotiate with us.

In connection with these license rights, the Company recorded $10,000, $30,000 and $20,000 as research and development expense in the years ended December 31, 2004, 2003 and 2002 respectively. In addition, we are obligated to pay Lawrence Berkeley National Lab a fee during 2005 in exchange for the election to retain the broad field. We are also required to pay Lawrence Berkeley National Lab earned royalties on products, services and processes covered by the license and sold by us or our affiliates or sublicensees, a percentage of certain other income received by us from our sublicensees, and patent prosecution and maintenance costs. To the extent that earned royalties in any given year do not meet certain threshold amounts, we are required to make annual minimum royalty payments to Lawrence Berkeley National Lab, ranging from $30,000 to $60,000, in order to maintain the license.

In order to maintain our license, we must expend at least $1.0 million per year commencing with 2005 towards the research, development and commercialization of products covered by the agreement. If we fail to do so, Lawrence Berkeley National Lab may renegotiate the milestones, terminate the agreement or convert the exclusive license to a non-exclusive license. In order to maintain the broad field, we must expend an additional amount during 2005 towards the research, development and commercialization of products and processes covered by the license. If we fail to expend such amount during calendar year 2005, Lawrence Berkeley National Lab may elect to accept substitute milestones achieved during calendar year 2005, negotiate additional milestones for calendar year 2006, or terminate our rights to the broad field. If our rights to the broad field terminate, the field will narrow to three therapeutic applications that we select from an agreed upon list, each to be more thoroughly defined through negotiation with Lawrence Berkeley National Lab.

We are obligated to indemnify Lawrence Berkeley National Lab, the United States government and related parties from claims arising from our or our sublicensees' exercise of rights under the agreement, unless the claims result from the indemnified parties' gross negligence or willful misconduct.

The agreement expires upon the later of the expiration, abandonment or final adjudication of invalidity of the licensed patents. The licensed patents consist of two United States patents that expire in 2017 and one United States patent application. Any patent issuing from such application will have a term of 20 years from the date such application was filed. Our license to use the know-how acquired from Lawrence Berkeley National Lab is paid-up and perpetual following the expiration, but not an earlier termination, of the agreement. Either party may terminate the agreement for the other's material breach with a 90 day cure period, although Lawrence Berkeley National Lab may terminate if we do not cure payment breaches within 30 days. We may terminate the agreement for any reason upon 180 days notice. Upon termination of the agreement, we are required to assign each sublicense to Lawrence Berkeley National Lab and Lawrence Berkeley National Lab is required to assume it unless the sublicensee is then in breach or the sublicense conflicts with Lawrence Berkeley National Lab's obligations to state or federal governments.

Manufacturing

We do not own facilities for manufacturing any products. Although we intend to rely on contract manufacturers, we have personnel with manufacturing experience to oversee the production of M-Enoxaparin, M-Dalteparin, M118 and future products that we may develop.

In each of our agreements with contract manufacturers, 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 contract manufacturer 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. In each contract, we have the right to terminate for convenience. The agreements also contain typical provisions for both parties to terminate for material breach and bankruptcy and insolvency.

M-Enoxaparin

In October 2003, we entered into a process development and production agreement with Siegfried (USA), Inc. and Siegfried Ltd. that was subsequently amended in 2004 and 2005. Under this agreement, we provided to Siegfried our existing laboratory-scale processes and analytical methods for the production of M-Enoxaparin. Siegfried's responsibility is to further develop the processes and upon our approval of such processes, manufacture the active pharmaceutical ingredient, enoxaparin sodium, for use in stability, preclinical and clinical studies and for other development purposes.

During the term of the agreement and for a period of time thereafter, Siegfried commits to work with us on the development and production of M-Enoxaparin on an exclusive basis. The Company recorded $0.8 million and $0.1 million as research and development expense for services from Siegfried during the years ended December 31, 2004 and 2003, respectively.

Under the agreement, we retain ownership of our intellectual property we provide to Siegfried and we exclusively own all intellectual property that is developed or made and/or reduced to practice by Siegfried pursuant to the agreement and that pertains to M-Enoxaparin. Further, Siegfried granted us, in order to develop, make, use, sell and import M-Enoxaparin, a non-exclusive, worldwide, irrevocable, sublicensable, royalty-free license to Siegfried's previously existing intellectual property and to intellectual property acquired by Siegfried apart from the agreement. To the extent that any of the intellectual property developed under the agreement has application to products other than heparins, we granted Siegfried, in order to develop, make, use, sell and import products that are not heparins, a non-exclusive, worldwide, irrevocable, non-sublicensable, royalty-free license to such intellectual property.

Siegfried is obligated to indemnify us for third-party product liability claims which result from the failure of the product to meet certain requirements and/or the negligence or misconduct of Siegfried. We are obligated to indemnify Siegfried for all other third-party product liability claims which result from the production, use or consumption of the product. In connection with the development and production of the product, Siegfried is obligated to indemnify us for any alleged infringement of any patent or other intellectual property right by a third party which results from a breach of certain intellectual property representations and warranties made by Siegfried. In connection with the development and production of the product, we are obligated to indemnify Siegfried for all other alleged infringements of any patent or other intellectual property right by a third party.

The agreement expires upon the completion of the development and production of the product. Either party may terminate the agreement: for the other's material breach which is not cured within 15 days; if such party reasonably determines that, for valid scientific or technical reasons, the goals of the agreement cannot be achieved within the agreed upon parameters or timelines and a modification is not agreed upon within 30 days; and, to the extent permitted by law, if the other party opens bankruptcy proceedings, goes into receivership, or allows its creditors to place the company in receivership. In addition, if unforeseen circumstances render the development and production materially more costly and we do not agree to an increase in the amount payable to Siegfried, Siegfried has the right to treat such decision as a valid scientific or technical obstacle and terminate the agreement. We may also terminate the agreement for any reason upon 30 days notice.

We are working with contractors to produce M-Enoxaparin in finished dose form for development and clinical use. In the course of developing M-Dalteparin, M118 and any other products, we are either currently working with or will enter into additional contractor outsourcing arrangements.

Sales and Marketing

We do not currently have any sales and marketing capabilities. In order to commercialize any products that are approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience. As our development candidates near commercialization, we may build a small, highly-focused, specialty sales and marketing infrastructure. Given that most of our products address patients who are either hospitalized or recently discharged from the hospital, we intend to focus our sales and marketing capabilities in these areas. In addition, we plan to enter into collaborations with established industry participants in key markets outside North America, including the European Union and Asia.

Competition

The development and commercialization of pharmaceutical products is highly competitive. In the event that we were to market and sell M-Enoxaparin, we would face competition from Sanofi-Aventis, the company currently marketing Lovenox, and potentially from other firms marketing 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 and Teva, and other ANDAs or other regulatory applications may be submitted in the future. Any generic enoxaparin application must demonstrate that its product has the same active ingredients as Lovenox, in accordance with the FDA's requirement for therapeutic equivalence and to be considered interchangeable with Lovenox. We believe that other firms submitting ANDAs will face difficulty in demonstrating that their products have the same active ingredients as Lovenox, given the challenges associated with the detailed analysis of Lovenox. M-Dalteparin will face competition from Pfizer, the company currently marketing Fragmin, and other manufacturers seeking to commercialize generic versions of Fragmin in the United States.

In addition, other anticoagulants used in the treatment of DVT and ACS will compete with our M-Enoxaparin, M-Dalteparin and M118 products. These competitors include:

- Glaxo-SmithKline's factor Xa inhibitor, Arixtra®, which is approved in multiple DVT indications;
- The Medicines Company's direct thrombin inhibitor, Angiomax®, which is approved for use in angioplasty;
- AstraZeneca's direct thrombin inhibitor Exanta® (European approval only); and
- Various UFH products.

We are aware of other anticoagulant drugs in development, including several factor Xa inhibitors in clinical trials. M118 also faces competition from products other than heparins, such as anti-platelet and direct thrombin inhibitors which may be used in the treatment of ACS.

In the field of glycoproteins, there are several competitors seeking to provide additional characterization or create improved versions and/or generic versions of marketed biologic products. GlycoFi, Inc., Neose Technologies, Inc. and Procognia Limited all possess selected sugar analytic and engineering capabilities which could be applied to creating improved or generic versions of biologics. Companies such as Teva, Sandoz, BioGenerix AG, Dragon Pharma, Stada and GeneMedix have all disclosed intentions to develop and commercialize generic and/or improved versions of marketed biologics. Some of these companies have experience with manufacturing complex biologics already or with commercializing generic products. Biotechnology and pharmaceutical companies also continue to invest significantly in better understanding their own products or creating improved versions of marketed products.

In the area of non-invasive drug delivery, there are many companies seeking to advance pulmonary delivery for therapeutic proteins. Current companies active in the drug delivery field include

Alkermes Inc., Aradigm Corporation, Sanofi-Aventis, Eli Lilly and Co., Nektar Therapeutics, Novo Nordisk A/S and Pfizer. In addition, there are many major pharmaceutical firms that may pursue non-invasive delivery as line extension strategies for existing products. These companies could become competitors or collaborators for our inhaled product portfolio.

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. Companies competing most directly with our approach of developing sugar-based therapeutics for oncology include GlycoGenesys Inc. and Progen.

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. In addition to major pharmaceutical and biotechnology companies which have successfully improved products through sugar modification, such as Amgen and Biogen Idec Inc., potential competitors with broad glycobiology capabilities include BioTie Therapies Oyj, GLYCART Biotechnology, GLYCO Design Inc., GlycoFi, Inc., Neose Technologies, Inc., Procognia Limited and Pro-Pharmaceuticals, Inc. Many of these companies are focused on providing services to pharmaceutical companies rather than focused on drug discovery and product development.

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 total of 14 United States patents and 29 United States patent applications as well as 17 foreign patents and 64 foreign patent applications which are counterparts to certain of the United States patents and patent applications. Our patent portfolio includes claims covering: methods and technologies for characterizing sugars; the use of certain naturally occurring heparinases, heparinase variants and other enzymes which specifically recognize polysaccharides in the characterization of sugars; methods and technologies for chemical and metabolic synthesis of sugars; the composition of matter of certain novel LMWHs, including M118, and heparinase variants; methods to produce and identify sugars associated with glycoproteins; 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 consist of patents and patent applications that are owned and licensed to us by M.I.T. The claims in our patent portfolio covering the methods and technologies for metabolic synthesis of sugars consist of patents and patent applications that are owned and licensed to us by Lawrence Berkeley National Lab.

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 both our generic 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.

Regulatory and Legal Matters

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import 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. A new drug will follow the NDA route, a new biologic will follow the BLA route, and a drug that claims to be the same as an already approved drug may be able to follow the ANDA route. Medical devices are approved or cleared for marketing through either the premarket approval application process, or PMA process, or the premarket notification process, or 510(k) clearance process. Drugs or biologics that are combined with medical devices may be regulated as combination products through one or more of the FDA's regulatory pathways.

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 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;
- 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 current Good Manufacturing Practices, or 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 under specific protocols and the supervision of qualified investigators. Each clinical 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 I trials usually involve the initial introduction of the investigational drug into humans to evaluate the product's safety, dosage tolerance and pharmacodynamics and, if possible, to gain an early indication of its effectiveness.

Phase II 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 III trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population. Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or we 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 criteria 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. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. 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 Process

FDA approval is required before a generic equivalent of an existing brand name drug can 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. Although the FDA has accepted ANDAs for generic versions of Lovenox for review, the FDA could determine that therapeutic equivalence cannot be shown for M-Enoxaparin and require an NDA for approval. 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 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 the same conditions of use as 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 active ingredients in the generic drug are the same pharmacological or therapeutic class as those of the listed drug and that the generic drug can be expected to have the same therapeutic effect as the listed drug 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.

Determination of the "sameness" of the active ingredients to that in the 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 of demonstrating chemical equivalence is relatively straightforward for small molecule drugs, it is inherently more difficult to define active ingredients for complex drugs, including those made from naturally occurring biological substances. These include heparins, therapeutic proteins, vaccines and antibiotics. The FDA has not reached a final position or provided specific guidance for demonstrating chemical equivalence for many of these products as criteria are in many cases, still evolving. There is currently no abbreviated approval mechanism for biologic products approved as BLAs. The FDA has stated it expects to produce some concept papers and draft guidance on the legal and scientific aspects of follow-on biologic regulation in the next several months, but Congressional action will likely be necessary to establish the regulatory pathway.

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 few patients. Under current regulations, for certain drug products where bioequivalence is self-evident such as injectable solutions which have been shown to contain the same active and inactive ingredients as the listed drug, the FDA may waive the requirement for *in vivo* bioequivalence data. Thus, most generic injectable products approved to date have been able to successfully obtain waivers to bioequivalence testing in humans.

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 approving generic products. In addition, submission of an ANDA for a drug that was a new molecular entity when approved 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 does not apply to M-Enoxaparin and M-Dalteparin 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, the FDA may now extend the exclusivity of a product by six months past the date of patent expiry if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension.

Combination Product Regulation

Products that are a combination of more than one jurisdictional product type, for example, drug/medical device combinations that are integrated as a whole or combined by co-packaging or co-labeling, may require more than one product approval, and/or the premarket review and postmarket regulation of more than one center at the FDA, possibly resulting in an uncertain approval path. Development and commercialization of our pulmonary formulations could in some instances require modification of the design or labeling of a legally available medical device, in which case the FDA may regulate the drug and delivery device as a combination product and/or require approval or clearance for the modified device. In addition, to the extent the delivery device is owned by a separate company, that company's cooperation would be required to obtain the necessary changes to the delivery device and any additional clearances or approvals. If no appropriate delivery device is available, we might have to develop and obtain clearance or approval of the delivery device itself. While such a delivery device could be approved as part of an NDA approval, it could also be subject to the medical device premarket submission process, or could be subject to both.

Approval or Clearance of Medical Devices

Diagnostic products like our future sugar-based discovery product for diagnosing prostate cancer would be evaluated as a medical device, either through the PMA process or the 510(k) clearance process, depending on whether the test is substantially equivalent to a legally marketed device. Gathering clinical evidence for diagnostic devices often does not, but may require submitting an investigational device exemption application to the agency, which in practice requires approval from the FDA within 30 days. Such testing is also subject to IRB approval and oversight. PMA approval typically requires, among other things, the submission of valid scientific evidence in the form of preclinical and clinical data, and a pre-approval inspection to determine if the manufacturing facility complies with cGMP practices under the quality system regulation that governs the design and all elements of the manufacture of devices. To demonstrate substantial equivalence, a 510(k) must show that the device is as safe and effective as an already legally marketed device, also known as a predicate device. The evaluation of the newer device must not raise different questions of safety and effectiveness than that of the predicate device. 510(k)s normally do not, but sometimes do require clinical data for clearance.

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, BLA or PMA, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy.

In addition, holders of an approved NDA, BLA, PMA, ANDA or cleared 510(k) 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. We use, and will continue to use in at least the near term, third-party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct.

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 and the generic company intends to market the generic equivalent prior to the expiration of that patent, the generic company includes a certification asserting that the patent is invalid, unenforceable and/or not infringed, a so-called "paragraph IV certification."

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 company filing a generic application is required to send the patent holder and the holder of the NDA for the brand-name drug a notice explaining why it believes that the patents in question are invalid, unenforceable or not infringed. Upon receipt of the notice from the generic applicant, the patent holder has 45 days during which to bring a patent infringement suit in federal district court against the generic applicant in order to obtain the 30 month automatic stay.

If a suit is commenced by the patent holder during the 45-day period, 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. Patent holders may only obtain one 30 month stay with respect to patents that were listed at the time an ANDA was filed. The period during which the FDA may not approve the ANDA and the patent challenger therefore may not market the generic product is 30 months, or such other period as may be ordered by the court. The 30-month period may or may not, and often does not, coincide with the timing of the resolution of the lawsuit or the expiration of a patent, but if the patent challenge is successful or the challenged patent expires during the 30-month period, the FDA may approve the generic drug for marketing, assuming there are no other obstacles to approval such as periods of non-patent exclusivity given to the NDA holder.

Under the Hatch-Waxman Act, any developer of a generic drug that is considered first to have filed its ANDA for review by the FDA, and whose filing includes a paragraph IV certification, may be eligible to receive a 180-day period of generic market exclusivity. 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. If the ANDA of the first applicant accepted for filing is withdrawn, the 180-day exclusivity period is forfeited and unavailable to any other applicant.

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. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable 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 may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

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. 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 hazardous materials and chemicals, including sodium azide, cetylpyridinium chloride monohydrate, 4-chlorobenzyl chloride, sodium nitrite pyridine, sodium cyanoborohydride and barium acetate. 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, 2004, we had 65 employees, including a total of 23 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.

RISK FACTORS THAT MAY AFFECT RESULTS

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, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, selling, general and administrative expenses, research and development expenses and the sufficiency of our cash for future operations. Forward-looking statements may be identified by the use of forward-looking terminology such as "believe," "may," "could," "will," "expect," "estimate," "anticipate," "continue," 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, 2004, our accumulated deficit was approximately $51.9 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 drug candidates we 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 for which we are only in the preliminary stages: developing drugs, obtaining regulatory approval for them, and manufacturing, 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 depress the market price of our common stock 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 of 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 candidate, M-Enoxaparin, a technology-enabled generic version of Lovenox. Our near-term ability to generate revenues and our future success, in part, depends on the development and commercialization of M-Enoxaparin.

In conjunction with Sandoz, we plan to prepare and submit an ANDA to the FDA seeking to produce and market M-Enoxaparin in the United States. FDA approval of our application is required

before marketing a generic equivalent of a drug previously approved under an NDA. If we are unable to obtain FDA approval for, and successfully commercialize M-Enoxaparin, we may never realize revenue from this product and we may have to curtail our other product development programs. As a result, our business would be materially harmed.

We will likely face intellectual property litigation with Sanofi-Aventis, the innovator of Lovenox.

Should we file a paragraph IV certification with our ANDA and thus attempt to commercialize M-Enoxaparin before expiration of the '618 patent, we will likely face costly and time consuming intellectual property litigation with Sanofi-Aventis, the innovator of Lovenox. Companies that produce branded pharmaceutical products for which there are unexpired patents listed in the FDA's Orange Book routinely bring patent infringement litigation against applicants seeking FDA approval to manufacture and market generic forms of their branded products before patent expiration. In August 2003, Sanofi-Aventis sued Amphastar and Teva, alleging, among other things, that the generic versions of Lovenox intended to be marketed by those companies infringe Sanofi-Aventis' '618 patent, which is scheduled to expire on February 14, 2012. We expect to face patent litigation if and when we submit a paragraph IV certification with our regulatory application for a generic version of Lovenox to the FDA. Litigation often involves significant expense and could delay or prevent the introduction of a generic product. Under most circumstances, the decision as to when to begin marketing M-Enoxaparin will be determined jointly by us and Sandoz. Sandoz, however, has sole discretion over the decision whether to market M-Enoxaparin under certain circumstances.

Sandoz has agreed to indemnify us for patent liability damages, subject to Sandoz's ability 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. Intellectual property litigation involves many risks and uncertainties, and there is no assurance that we will prevail in any lawsuit brought by Sanofi-Aventis. In addition, Sanofi-Aventis has significantly greater resources than we do, and litigation with Sanofi-Aventis could last a number of years, potentially delaying or prohibiting the commercialization of M-Enoxaparin. If we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, we may have to curtail our product development programs and our business would be materially harmed.

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

Some of our products in current or future development may be based on new technologies that have not been formally reviewed or accepted by the FDA or other regulatory authorities. Given the complexity of our technology, we intend to work closely with the FDA and other regulatory authorities to perform the requisite scientific analysis and evaluation of our methods to obtain regulatory approval for our products. It is possible that the validation process may take time and resources, require independent third-party analysis or not be accepted by the FDA and other regulatory authorities. For some 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.

We will need to develop or acquire additional technologies as part of our program to analyze the branched sugars found on glycoprotein products.

To date, our analytical techniques and methods have been primarily focused on the characterization of linear sugars, such as those found in the heparin class of drugs. In order to adequately analyze the branched sugars found on glycoproteins, we will need to develop or acquire new technologies. Our inability to develop or acquire, and apply these new technologies would limit our ability to work with innovator biotechnology companies to help them better understand the sugars

contained on their products, impair our ability to assist biotechnology companies in developing improved and next generation versions of existing glycoprotein products, and limit our ability to perform the analysis that we believe may be required to enable follow-on biologics. Our inability to adequately analyze these branched sugars could reduce the value of our glycoprotein program.

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

In mid 2003, Amphastar and Teva each filed ANDAs for generic versions of Lovenox with the FDA. In addition, other third parties may seek approval to manufacture and market generic versions of Lovenox in the United States prior to our ANDA filing. If any of these parties obtain FDA approval under ANDA guidelines, we may not gain any competitive advantage. Also, we may never achieve significant market share for M-Enoxaparin. Consequently, our revenues would be reduced and, as a result, our business, including our future discovery and development programs, would suffer. In addition, under the Hatch-Waxman Act, any developer of a generic drug that is considered first to have its ANDA accepted for review by the FDA, and whose filing includes a paragraph IV certification, may be eligible to receive a 180-day period of generic market exclusivity. In the event that any eligible 180-day exclusivity period has not begun and/or expired at the time we receive tentative approval for M-Enoxaparin, we may be forced to wait until the expiration of the exclusivity period before the FDA could make our approval effective.

If we fail to meet manufacturing requirements for M-Enoxaparin, 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 have entered into an agreement with Siegfried (USA), Inc. and Siegfried Ltd., pursuant to which Siegfried is manufacturing the drug substance for M-Enoxaparin and is providing certain other services relating to M-Enoxaparin. We depend on additional third parties to manufacture the drug product and provide analytical services with respect to M-Enoxaparin. We have not yet filed our ANDA, including information on our manufacturing lots, and we or our third-party manufacturers, may encounter difficulties that may cause a delay in the filing.

In addition, if the product is approved, in order to produce M-Enoxaparin in the quantities necessary to meet anticipated market demand, we and any contract manufacturer that we engage will need to increase manufacturing capacity. If we are unable to produce M-Enoxaparin 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.

Our revenues and profits from any of our generic product candidates may decline if our competitors introduce their own generic equivalents.

In addition to general competition in the pharmaceutical market, we expect that certain of our generic product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. Revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. 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 competing off-patent manufacturers receive regulatory approvals on similar products or as branded manufacturers launch 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, 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.

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, preclinical testing, conducting clinical trials, obtaining regulatory approvals, challenging patents and in 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 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 timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the effectiveness of our marketing and sales capabilities;
- the price of our products;
- the availability and amount of third-party reimbursement; 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 our key customer arrangements, sales of our products and revenues would decline.

Most generic pharmaceutical products are sold to customers through arrangements with group purchasing organizations, or GPOs. Generic pharmaceuticals are also sold through arrangements with retail organizations, mail order channels and other distributors. Many of the hospitals which make up M-Enoxaparin's target market contract with the GPO of their choice for their purchasing needs. We expect to derive a large percentage of our future revenue for M-Enoxaparin from customers that have relationships with a small number of GPOs. Currently, a relatively small number of GPOs control a large majority of sales to hospital customers. In order to establish and maintain relationships with major GPOs, we believe we 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 relationships may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours. Typically, GPO agreements may be terminated on short notice. If we are unable to establish and maintain arrangements with major GPOs and customers, sales of our products, revenues and profits would decline.

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 of our physician education and marketing programs;
- the sales and marketing efforts of competitors; and
- the availability and amount of government and third-party payor reimbursement.

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

We 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.

We will continue to require substantial funds to conduct research and development, process development, manufacturing, preclinical testing and clinical trials of our development 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 progress of development of M-Enoxaparin, M-Dalteparin, our glycoprotein program and M118;
- the cost of litigation, including potential patent litigation with Sanofi-Aventis relating to Lovenox, or with others, as well as any damages, including possibly treble damages, that may be owed to Sanofi-Aventis or others 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 anticipate that our current cash, cash equivalents and marketable securities, including $20.4 million in net proceeds received in connection with the issuance of our Series C convertible preferred stock in February 2004 and the $35.3 million in net proceeds from our initial public offering in June 2004 will be sufficient to fund our operations through the middle of 2007. We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and debt financings. Additional funds may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

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

We are dependent on the members of our senior management team, in particular, Ganesh Venkataraman, our Co-Founder and Vice President of Technology, for our business success. Our employment agreements with Dr. Venkataraman and our other executive officers are terminable 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, our growth will require us to hire a significant number of qualified scientific, commercial and administrative personnel. 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 we are unable to obtain sufficient insurance, a product liability claim against us 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, clinical or otherwise. 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. We are in the process of obtaining, but do not currently have any product liability insurance. Any insurance we obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain 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 the development of our drug candidates advance, we will need to expand our development, regulatory, manufacturing, 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. Such 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.

Acquisitions present many risks, and we may not realize the anticipated financial and strategic goals for any such transactions.

We may in the future acquire complementary companies, products and technologies. Such acquisitions involve a number of risks, including:

- we may find that the acquired company or assets do 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;
- we may have difficulty integrating the operations and personnel of the acquired business, and may have difficulty retaining the key personnel of the acquired business;
- we may have difficulty incorporating the acquired technologies;
- we may face product liability risks associated with the sale of the acquired company's products;
- our ongoing business and management's attention may be disrupted or diverted by transition or integration issues and the complexity of managing diverse locations;
- we may have difficulty maintaining uniform standards, controls, procedures and policies across locations;
- 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 (such as of acquired in-process research and development costs) 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.

Changes in stock option accounting rules may have a significant adverse affect on our operating results.

We have a history of using broad-based employee stock option programs to hire, provide incentive for and retain our workforce in a competitive marketplace. Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," allows companies the choice of either using a fair value method of accounting for options that would result in expense recognition for all options granted, or using an intrinsic value method, as prescribed by Accounting Principles Board

Opinion No. 25, "Accounting for Stock Issued to Employees," or APB 25, with a pro forma disclosure of the impact on net income (loss) of using the fair value option expense recognition method. We have elected to apply APB 25 and accordingly we generally have not recognized any expense with respect to employee stock options as long as such options are granted at exercise prices equal to the fair value of our common stock on the date of grant.

In December 2004, the Financial Accounting Standards Board issued "Share-Based Payment" (Statement 123(R)). Statement 123(R) requires that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity instruments issued. In determining the fair value of options and other equity-based awards, companies may use different valuation models that may involve extensive and complex analysis. Statement 123(R) will be effective for us no later than July 1, 2005, which is the first day of the third quarter of our 2005 fiscal year. We are in the process of reviewing Statement 123(R) to determine which model is more appropriate for us. We continue to evaluate the effect that the adoption of Statement 123(R) will have on our financial position and results of operations. We currently expect that our adoption of Statement 123(R) will adversely affect our operating results to some extent in future periods.

Risks Relating to Development and Regulatory Approval

If we are not able to demonstrate therapeutic equivalence for our generic versions of complex drugs, including our M-Enoxaparin and our M-Dalteparin products to the satisfaction of the FDA, we will not obtain regulatory approval for commercial sale of our generic product candidates and our future results of operations would 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, including M-Enoxaparin and M-Dalteparin. To obtain regulatory approval for the commercial sale of our generic versions of complex drugs, including M-Enoxaparin and M-Dalteparin, we will be required to demonstrate to the satisfaction of the FDA, among other things, that our generic products contain the same active ingredients, are of the same dosage strength, form, and route of administration, and meet compendial or other applicable standards for strength, quality, purity and identity, including potency. Our generic versions of complex drugs, including M-Enoxaparin and M-Dalteparin, must also be bioequivalent, meaning generally that there are no significant differences in the rate and extent to which the active ingredients are absorbed and become available at the site of drug action. Under current regulations, for certain drug products where bioequivalence is self-evident such as injectable solutions which have been shown to contain the same active and inactive ingredients as the listed drug, the FDA may waive the requirement for *in vivo* bioequivalence data.

Determination of the same active ingredients for M-Enoxaparin and M-Dalteparin will be based on our demonstration of the chemical equivalence of our generic versions to Lovenox and Fragmin, respectively. The FDA may require confirmatory information including, for example, animal testing, to determine the sameness of active ingredients and that any inactive ingredients or impurities do not compromise the product's safety and efficacy. Provision of sufficient information for approval may prove difficult and expensive. We must also demonstrate the adequacy of our methods, controls and facilities used in the manufacture of the product, including that they meet cGMP. We cannot predict whether any of our generic product candidates will meet FDA requirements for approval.

In the event that the FDA does not establish a standard for therapeutic equivalence with respect to generic versions of complex drugs, or requires us to conduct clinical trials or other lengthy processes, the commercialization of our technology-enabled generic product candidates could be delayed or prevented. 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 FDA is not able to establish specific guidelines or arrive at a consensus regarding the scientific capabilities for analyzing complex protein drugs, and if the U.S. Congress does not take action to create an abbreviated regulatory pathway for follow-on protein products, this will increase the uncertainty about the value of our glycoprotein program.

The regulatory climate for generic versions of protein products remains very uncertain. Currently there is no established statutory or regulatory pathway which provides the FDA with the authority to approve generic versions of most protein drugs. Most therapeutic protein drugs were approved by the FDA under the Public Health Services Act as BLAs. Unlike products approved as NDAs, there is no provision in the Public Health Service Act for an abbreviated application that would permit approval of a follow-on protein product, 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 a follow-on product. Moreover, even for proteins originally approved as NDAs, there is debate as to the data necessary to demonstrate the sameness required for ANDA approval. The FDA recently stated it anticipates drafting several guidances and concept papers to address the scientific and regulatory issues but that the development of many of these documents will take several months. It is anticipated that the U.S. Congress, based on guidance from the FDA, will establish a regulatory path sometime in the future for approval of generic versions of therapeutic protein products that were approved as BLAs. Failure of the FDA to establish standards or the U.S. Congress to enact legislation could reduce the value of our glycoprotein program.

If our preclinical studies and clinical trials for our development candidates 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 or improved drug candidates, we will be required to demonstrate through preclinical studies and clinical trials that our drug development candidates are safe and effective. Preclinical testing and clinical trials of new development candidates are lengthy and expensive and the historical failure rate for development candidates is high. The results from preclinical testing of a development candidate may not predict the results that will be obtained in human clinical trials. Clinical trials cannot commence until we submit an IND containing sufficient preclinical data and other information to support use in human subjects and the FDA allows the trials to go forward. Clinical trials must also be reviewed and approved by IRBs for each clinical trial site before an investigational new drug may be used in a human trial at that site. We, the FDA or other applicable regulatory authorities may prohibit the initiation of, or suspend clinical trials of, a development candidate at any time if we or they believe the subjects or patients participating in such trials are being exposed to unacceptable health risks, or for other reasons. Adverse side effects of a development candidate on subjects or patients in a clinical trial could result in the FDA or other regulatory authorities refusing to approve a particular development candidate for any or all indications of use.

Clinical trials of a new development candidate require the enrollment of a sufficient number of patients who are suffering from the disease the development candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial. Lower than anticipated patient enrollment rates, high drop-out rates or inadequate drug supply or other materials, can result in increased costs and longer development times.

We cannot predict whether any of our development candidates will encounter problems during clinical trials which will cause us or regulatory authorities to delay or suspend these trials, or which will delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative

changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate that is affected or the development of any of our other drug candidates.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products abroad.

Although we have not initiated any marketing efforts in foreign jurisdictions, we intend in the future to market our products outside 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 numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. 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 other foreign countries 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 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 drugs 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 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 regulatory requirements, we may be subject to recalls, warning letters, civil penalties, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions and/or criminal prosecutions and penalties.

If third-party payors do not adequately reimburse customers for any of our product candidates that are approved for marketing, 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 products 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 or Medicaid 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.

New 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, changes the way Medicare will cover and reimburse for pharmaceutical products. The legislation expands Medicare coverage for drug purchases by the elderly and will introduce a new reimbursement methodology based on average sales prices for drugs. In addition, the new legislation provides authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of the new legislation and the expansion of federal coverage of drug products, we expect continuing pressure to contain and reduce costs. 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 applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

Proposed federal legislation, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States which may include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition.

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

Many manufacturers of branded products have increasingly used both state and federal legislative and regulatory means to delay competition from manufacturers of generic drugs. These efforts have included:

- pursuing new patents for existing products which may be granted just before the expiration of one patent, which could extend patent protection for a number of years or otherwise delay the launch of generics;
- submitting Citizen Petitions to request the Commissioner of Food and Drugs to take administrative action with respect to prospective and filed generic applications;
- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug standards; and
- attaching special patent extension amendments to unrelated federal legislation.

In addition, some manufacturers of branded products have engaged in state-by-state initiatives to enact legislation that restrict 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.

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

In some foreign countries, particularly the countries of the European Union, the pricing 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, including sodium azide, cetylpyridinium chloride monohydrate, 4-chlorobenzyl chloride, sodium nitrite pyridine, sodium cyanoborohydride and barium acetate. For the years ended December 31, 2004, 2003, and 2002, we spent approximately $25,000, $17,500, and $10,000, 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 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. For claims not covered by workers' compensation insurance, we also maintain an employer's liability insurance policy in the amount of $3.5 million per occurrence and in the aggregate. 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 Our Dependence on Third Parties

Our collaboration with Sandoz is important to our business. If Sandoz fails to adequately perform under our collaboration or terminates our collaboration, the development and commercialization of injectable enoxaparin would be delayed or terminated and our business would be adversely affected.

In November 2003, we entered into a collaboration and license agreement with Sandoz to jointly develop and commercialize injectable enoxaparin and certain improved injectable forms of enoxaparin. Under the terms of the agreement, we and Sandoz agree to exclusively work with each other in the development and commercialization of injectable enoxaparin within the United States. If Sandoz fails to adequately perform under our collaboration and license agreement, we may not successfully commercialize M-Enoxaparin and may be precluded from seeking alternative collaborative opportunities because of our exclusivity commitment. We have also granted to Sandoz the right to negotiate additional rights under certain circumstances.

Sandoz may terminate our collaboration agreement for material uncured breaches or certain events of bankruptcy or insolvency by us. Sandoz may also terminate the collaboration 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 other than due to our uncured breach, 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. In such event, significant delays would be likely to occur and could prevent us from completing the development and commercialization of injectable enoxaparin.

If Sandoz terminates the agreement due to our uncured breach, Sandoz would retain the exclusive right to develop and commercialize injectable enoxaparin in the United States. In that event, although the profit sharing, royalty and milestone payment obligations of Sandoz would survive, we would no longer have any influence over the development or commercialization strategy. In addition, if Sandoz were to terminate the agreement due to our uncured breach, 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. Accordingly, if Sandoz terminates the agreement, 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 materially affect our business.

We depend on third-party manufacturers to manufacture products for us. If in the future we encounter difficulties in our supply or manufacturing arrangements, our business may be materially affected.

We have limited personnel with experience in, and we do not own facilities for, manufacturing any 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. For our M-Enoxaparin program, we have entered into an agreement with Siegfried (USA), Inc. and Siegfried Ltd., pursuant to which, among other things, Siegfried provides us with the M-Enoxaparin drug substance required for our ANDA filing. To develop our drug candidates, apply for regulatory approvals and commercialize any products, we or our

partners need to contract for or otherwise arrange for the necessary manufacturing facilities and capabilities. As a result, we would generally rely on contract manufacturers for regulatory compliance and quality assurance for our products. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or drug candidates could be delayed, which could have an adverse affect on our business. In addition, any change in our 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 studies and may continue to do so in the future. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term 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. Any failure by us 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.

We may need to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our drug candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business could be adversely affected.

Because we have limited or no capabilities for drug development, manufacturing, sales, marketing and distribution, we may need to enter into alliances with other companies that can assist with the development and commercialization of our drug candidates. We may, for example, form alliances with major pharmaceutical companies to jointly develop specific drug candidates and to jointly commercialize them if they are approved. In such alliances, we would expect our pharmaceutical company partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing. 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 if, for example, development or approval of a drug candidate is delayed or sales of an approved drug are disappointing. If we are unable to secure or maintain such alliances we may not have the capabilities necessary to continue or complete development of our drug candidates and bring them to market, which may have an adverse effect on our business.

In addition to 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 a particular drug candidate internally, or to bring drug candidates to market. Failure to bring our drug candidates to market will prevent us from generating sales revenues, and this may substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market. As a result, our business may be adversely affected.

If any collaborative partner terminates or fails to perform its obligations under agreements with us, the development and commercialization of our drug candidates could be delayed or terminated.

Our continued and expected dependence on collaborative partners for their drug development, manufacturing, sales, marketing and distribution capabilities, as well as for their financial support means that our business would be adversely affected if a partner terminates its collaboration agreement with us or fails to perform its obligations under the agreement. Our current collaborations and future collaborations, if any, may not be scientifically or commercially successful. 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 is approved for marketing, than to products from their own development programs.

If any of these occur, the development and commercialization of one or more drug candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization.

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 sales, marketing and 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 and 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.

Our collaborations with outside scientists and consultants may be subject to restriction and change.

We work with chemists, biologists and other scientists at academic and other institutions, and consultants who assist us in our research, development, regulatory and commercial efforts. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice on our programs. These scientists and consultants are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products.

We enter into various contracts in the normal course of our business that periodically incorporate provisions whereby we indemnify the other party to the contract. In the event we would have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial position and results of operations.

In the normal course of business, we periodically enter into academic, commercial and consulting agreements that contain indemnification provisions. With respect to our academic agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, including those with contract manufacturers, we indemnify our vendors from third party product liability claims which result from the production, use or consumption of the product, as well as for certain alleged infringements of any patent or other intellectual property right by a third party. With respect to consultants, we indemnify them from claims arising from the good faith performance of their services. We do not, however, typically indemnify parties for claims resulting from the gross negligence or willful misconduct of the indemnified party.

We maintain insurance coverage which we believe may limit our obligations under these indemnification provisions. With respect to M-Enoxaparin, we are also protected under certain circumstances through the indemnification provided to us by Sandoz. However, should our obligation under an indemnification provision fall outside the scope of our insurance coverage, exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial position and results of operations could be adversely affected and the market value of our common stock could decline. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial position and results of operations could be adversely affected.

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 United States 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.

Our competitors may allege that we are infringing their intellectual property, 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 parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to incur expenses to litigate the claims, pay damages, potentially including treble damages, if we are found to have willfully infringed such parties' patent rights. In addition, if we are unsuccessful in litigation, a court could issue a permanent injunction preventing us from marketing and selling the patented drug or other technology for the life of the patent that we have been deemed to have infringed. Litigation concerning patents, other forms of 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 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 enforce our patent rights, we could incur substantial costs, substantial liability for damages and be required to stop our product commercialization efforts.

We may need to resort to litigation to enforce a patent issued to us or to determine the scope and validity of third-party proprietary rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation 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 have substantially greater resources. 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 development, royalty and other obligations on us. If we breach these obligations, these exclusive licenses 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.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers, advisors and others. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

General Company Related Risks

If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market prices for securities of biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Some of the factors that may cause the market price of our common stock to fluctuate include:

- failure to obtain FDA approval for M-Enoxaparin or other adverse FDA decisions relating to M-Enoxaparin;
- litigation involving our company or our general industry or both, including potential litigation with Sanofi-Aventis relating to M-Enoxaparin;

- results of our clinical trials or those of our competitors;
- failure to demonstrate therapeutic equivalence with respect to our technology-enabled generic product candidates and safety and efficacy for our novel development product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- developments or disputes concerning our patents or other proprietary rights;
- our ability to manufacture any products to commercial standards;
- changes in estimates of our financial results or recommendations by securities analysts;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; and
- investors' general perception of our company, our products, the economy and general market conditions.

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.

Our directors, executive officers and major stockholders have substantial 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 76% of our outstanding common stock as of December 31, 2004. As a result, these stockholders, if acting together, may have the ability to determine the outcome of 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;
- 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;
- the ability of our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors 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.

Item 2. PROPERTIES

As of March 15, 2005, pursuant to our September 2004 sublease agreement, we are leasing a total of approximately 20,000 square feet of office and laboratory space in one building in Cambridge, Massachusetts and as contemplated by the September 2004 sublease agreement, in mid-2005, we expect to increase our leased space to 45,000 square feet within the same building. Our properties are described below:

Property Location	Approximate Square Footage	Use	Lease Expiration Date
675 West Kendall Street Cambridge, Massachusetts 02142	20,000	Laboratory & Office	04/30/2011

Item 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

PART II

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

Market Information

Prior to June 2004, there was no established market for our common stock. Since June 22, 2004, our common stock has been traded on the NASDAQ National Market under the symbol "MNTA." The following table sets forth the high and low last sale prices of our common stock for each of the quarters ending June 30, 2004 through December 31, 2004 as reported on the NASDAQ National Market:

Quarter ended	High	Low
June 30, 2004 (beginning June 22, 2004)	$8.85	$7.81
September 30, 2004	8.70	7.05
December 31, 2004	8.56	7.06

Holders

On March 14, 2005, the approximate number of holders of record was 72 and the approximate number of beneficial holders of our common stock was 653.

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.

Use of Proceeds

On June 25, 2004, we sold 5,350,000 shares, together with an additional 802,500 shares pursuant to the exercise by the underwriters of an over-allotment option, of our common stock in connection with the closing of our initial public offering. The Registration Statement on Form S-1 (Reg. No. 333-113522) we filed to register our common stock in our initial public offering was declared effective by the Securities and Exchange Commission on June 21, 2004.

All of the net proceeds of our initial public offering have been invested into investment-grade marketable securities. None of the net proceeds were directly or indirectly paid to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the Securities Exchange Commission pursuant to Rule 424(b).

Item 6. SELECTED FINANCIAL DATA

The selected financial data set forth below with respect to our statement of operations data for the years ended December 31, 2004, 2003 and 2002 and the balance sheet data as of December 31, 2004, and 2003 are derived from our audited financial statements included in this Annual Report on Form 10-K. The statement of operations data for the period from inception through December 31, 2001 and the balance sheet data as of December 31, 2002 and 2001 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 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 financial data set forth below should be read in conjunction with and is qualified in its entirety by our audited 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,			Period from Inception (May 17, 2001) through December 31, 2001
	2004	2003	2002	
	(In thousands, except per share information)			
Statements of Operations Data:				
Collaboration revenue	$ 7,832	$ 1,454	$ —	$ —
Operating expenses:				
Research and development	15,722	5,347	2,174	206
General and administrative	6,751	4,083	2,712	167
Total operating expenses	22,473	9,430	4,886	373
Loss from operations	(14,641)	(7,976)	(4,886)	(373)
Interest income	605	74	17	2
Interest expense	(39)	(43)	—	—
Net loss	(14,075)	(7,945)	(4,869)	(371)
Deemed dividend related to beneficial conversion feature of Series C redeemable convertible preferred stock	(20,389)	—	—	—
Dividends and accretion to redemption value of redeemable convertible preferred stock	(1,852)	(1,898)	(520)	(22)
Net loss attributable to common stockholders	$(36,316)	$(9,843)	$(5,389)	$ (393)
Basic and diluted net loss per share attributable to common stockholders	$ (2.56)	$ (5.02)	$ (5.70)	$(6.74)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	14,177	1,961	946	58

	As of December 31,			
	2004	2003	2002	2001
Balance Sheet Data:				
Cash and cash equivalents	$ 11,678	$ 4,613	$ 1,471	$ 181
Marketable securities	41,943	7,994	—	—
Working capital	54,154	13,044	633	(128)
Total assets	64,330	16,084	2,500	184
Line of credit obligation—net of current portion	1,105	372	—	—
Redeemable convertible preferred stock	—	27,225	6,427	22
Accumulated deficit	(51,944)	(15,628)	(5,785)	(396)
Total stockholders' equity (deficit)	56,993	(13,779)	(4,831)	(148)

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

Our management's discussion and analysis of our financial condition and results of operations include the identification of certain trends and other statements that may predict or anticipate future business or financial results that are subject to important factors that could cause our actual results to differ materially from those indicated. See "Risk Factors."

Overview

Momenta is a biotechnology company specializing in the detailed structural analysis and design of complex sugars for the development of improved versions of existing drugs, the development of novel drugs and the discovery of new biological processes. We are also utilizing our ability to sequence sugars to create technology-enabled generic versions of sugar-based and biologic drug products. Through detailed analysis of the molecular structure of complex sugars, we believe our proprietary technology enables us to define the specific sugar sequences contained in complex sugar-based drugs, including those structures that had previously not been described due to a lack of available technology. In addition, we are able to derive a more complete understanding of the roles that sugars play in cellular function, disease and drug action based on our structural and biological analytic capabilities. With our capabilities for understanding complex sugars, we have developed a diversified pipeline of near-term product opportunities and novel discovery and development candidates.

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox, a widely prescribed LMWH. We have formed a collaboration with Sandoz to jointly develop, manufacture and commercialize M-Enoxaparin. In addition, we are developing M-Dalteparin, a technology-enabled generic version of Fragmin, another LMWH. We are also applying our technology to the analysis of branched sugars on proteins, or glycoproteins. We believe our technology can be used to better understand existing marketed protein drugs, modify the complex sugars on therapeutic proteins to improve their efficacy, dosing, and safety profile, and to facilitate the development of equivalent versions of these products. This may yield multiple additional product opportunities, including working with innovator companies to assist them with creating improved versions of protein therapeutics and working with companies seeking to develop follow-on protein products.

Since our inception in 2001, we have incurred annual net losses. As of December 31, 2004, we had an accumulated deficit of $51.9 million. We recognized net losses of $14.1 million, $7.9 million and $4.9 million for the years ended December 31, 2004, 2003 and 2002, 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 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, 2004 and 2003 of $7.8 million and $1.5 million, respectively, were derived from our collaboration agreement with Sandoz and primarily consist of amounts earned by us for reimbursement by Sandoz of research and development services and development costs for M-Enoxaparin. On June 25, 2004, we completed an initial public offering of our common stock, the net proceeds of which were $35.3 million after deducting underwriters' discounts and expenses. In February 2004, we raised net cash proceeds of $20.4 million from the sale of Series C redeemable convertible preferred stock. We have devoted substantially all of our capital resources to the research and development of our product candidates.

The biotechnology and pharmaceutical industries 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. 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 for which we are only in the preliminary stages: developing drugs, obtaining regulatory approval for them, and manufacturing, marketing and selling them. 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. Our successful development and commercialization of M-Enoxaparin, in collaboration with Sandoz, will depend on several factors, including: using our technology to meet FDA criteria to demonstrate that M-Enoxaparin is therapeutically equivalent to Lovenox; manufacturing M-Enoxaparin for FDA approval and commercialization; the outcome of potential litigation with Sanofi-Aventis relating to enoxaparin, if any; and our ability to market M-Enoxaparin and achieve acceptance of M-Enoxaparin in the medical community and with third-party payors.

Financial Operations Overview

Revenue

We have not yet generated any revenue from product sales and do not expect to generate any revenue from the sale of products over the next several years. We have recognized, in the aggregate, $9.3 million of revenue from our inception through December 31, 2004. This revenue was derived entirely from our collaboration agreement with Sandoz. 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 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.

The following summarizes our primary research and development programs.

M-Enoxaparin. Our most advanced product, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox. We have formed a collaboration with Sandoz to jointly develop, manufacture and commercialize M-Enoxaparin. Under our collaboration agreement, Sandoz is responsible for funding substantially all of the M-Enoxaparin development, regulatory, legal and commercialization costs. The total cost of development and commercialization and the timing of bringing M-Enoxaparin to market is subject to uncertainties relating to the development, regulatory approval and legal processes.

M-Dalteparin. M-Dalteparin is designed to be a technology-enabled generic version of Fragmin. Our development, regulatory, and commercialization strategies for M-Dalteparin are similar to those of M-Enoxaparin. As a result, the total cost of development and commercialization and the timing of bringing M-Dalteparin to market is subject to similar uncertainties relating to the development and regulatory approval processes.

Glycoproteins. We are applying our technology to analyze and quantify the specific complex sugars found on therapeutic protein drugs. We believe our technology can be used to better understand existing marketed protein drugs and to facilitate the development of equivalent versions of these products. We believe our analytic and engineering capabilities can also enable the development of complex sugars on therapeutic proteins to improve the efficacy, reduce side effects and modify the dosage of protein drugs.

M118. M118 is a LMWH that was rationally designed to provide improved anti-clotting activity and flexible administration to treat patients with ACS. M118 is currently in preclinical development. We expect that additional expenditures will be required to complete preclinical testing and, if such preclinical testing is successful and we do not encounter other difficulties, we intend to file an IND and begin Phase I clinical trials shortly thereafter. Because M118 is in preclinical development, we are unable to estimate the cost to complete the research and development phase nor are we able to estimate the timing of bringing M118 to market.

Other Development Opportunities. Other research programs include a sugar-mediated technology that improves the non-invasive delivery of therapeutic proteins and our drug discovery program, in which we are applying our understanding of sugar biology to develop sugar-based drugs and identify specific biological processes and pathways that can be targeted with small molecules and antibody drugs, focused initially on oncology.

General and Administrative

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

We anticipate additional increases in general and administrative expense to support increases in research and development programs. These increases will likely include the hiring of additional personnel. We intend to continue to incur increased internal and external business development costs to support our various product development efforts, which can vary from period to period.

Results of Operations

Years Ended December 31, 2004, 2003 and 2002

Revenue

Revenue for 2004 was $7.8 million, compared with $1.5 million for 2003 and no revenues in 2002. The increase of $6.3 million from 2003 to 2004 is attributable to our collaboration agreement with Sandoz signed in November 2003. This revenue includes amortization of an initial payment made to us by Sandoz and amounts earned for research and development services and other reimbursable costs.

Research and Development

Research and development expense for 2004 was $15.7 million compared with $5.3 million in 2003 and $2.2 million in 2002. The increase of $10.4 million from 2003 to 2004 principally resulted from an increase of $4.8 million of expenses associated with the M-Enoxaparin program, including an increase of $1.9 million in personnel and related costs and an increase of $2.5 million in contracted costs for manufacturing process development, an increase of $3.1 million of expenses for the M118 program, including an increase of $1.1 million in personnel and related costs and $1.6 million for manufacturing process development, and an increase of $1.1 million for the drug delivery program, including an increase of $0.8 million in personnel and related expenses. The increase of $3.1 million in research and development expense from 2002 to 2003 principally resulted from an increase of $3.0 million of

expenses associated with the M-Enoxaparin program, reflecting an increase of $1.2 million in personnel and related costs and an increase of $1.6 million in contracted costs for manufacturing process development, and the initiation of the M118 program in 2003. In addition, research and development expenses in 2002 included charges totaling $0.6 million for license fees.

The following table summarizes the primary components of our research and development expenses for our principal research and development programs for the years ended December 31, 2004, 2003 and 2002.

Research and Development Program (in thousands)	2004	2003	2002
M-Enoxaparin	$ 8,732	$3,928	$ 961
M118	3,635	542	—
Drug delivery	1,425	300	—
Other discovery and development programs	1,930	577	1,213
Total research and development expense	$15,722	$5,347	$2,174

General and Administrative

General and administrative expense for the year ended December 31, 2004 was $6.8 million compared to $4.1 million in 2003 and $2.7 million in 2002. In 2004 compared to 2003, general and administrative expense increased by $2.7 million due primarily to an increase of $0.5 million in stock compensation expense, an increase of $0.7 million in personnel costs and $0.3 million in facility costs due to increased headcount, an increase of $0.7 million in professional fees, including consulting and accounting fees and an increase of $0.4 million in insurance costs. In 2003 compared to 2002, general and administrative expense increased due to an increase of $0.3 million in stock compensation expense, an increase of $0.8 million in personnel costs due to increased headcount and an increase of $0.3 million in legal costs due to an increase in corporate and patent-related legal services.

Interest Income

Interest income increased to approximately $605,000 in the year ended December 31, 2004 from $74,000 in 2003, primarily due to higher average investment balances as a result of the proceeds from our initial public offering in June 2004. Interest income increased to $74,000 in 2003 from $17,000 in 2002, primarily due to higher average investment balances as a result of the proceeds from our issuance of Series B preferred stock in May 2003.

Interest Expense

Interest expense of approximately $39,000 in the year ended December 31, 2004 and $43,000 in 2003 related to amounts drawn from our bank line of credit. There were no borrowings and no interest expense in 2002.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of equity securities, payments from our collaboration agreement with Sandoz and borrowings from our lines of credit. As of December 31, 2004, since our inception we have received net proceeds of $45.4 million from the issuance of redeemable convertible preferred stock. In addition, on June 25, 2004 we completed our initial public offering and raised net proceeds of $35.3 million. As of December 31, 2004, we have also received $4.7 million from our Sandoz collaboration, $2.5 million from debt financing and additional funds from interest income.

At December 31, 2004, we had $53.6 million in cash, cash equivalents and marketable securities. In addition, we hold $1.5 million in restricted cash which serves as collateral for a letter of credit related to our facility lease. During the years ended December 31, 2004, 2003 and 2002, our operating activities used $12.6 million, $8.0 million and $3.7 million, respectively. The use of cash in each period was primarily a result of net losses associated with our research and development activities and amounts incurred to develop our administrative infrastructure.

Net cash used in investing activities was $37.2 million, $8.5 million and $1.0 million for the years ended December 31, 2004, 2003 and 2002, respectively. During 2004, we used $64.9 million of cash to purchase marketable securities, offset by cash provided from $29.8 million in maturities of marketable securities. We used $8.0 million of cash in 2003 to purchase short-term investments. In the years ended December 31, 2004, 2003 and 2002, we used $2.1 million, $0.5 million and $1.0 million, respectively, to purchase equipment and leasehold improvements.

For the year ended December 31, 2004, our financing activities provided $56.9 million, reflecting the net proceeds of $35.3 million from our initial public offering in June, 2004 and the issuance of our Series C redeemable convertible preferred stock for net proceeds of $20.4 million. In addition, in December 2004, we entered into a new line of credit with a bank primarily to finance the purchase of equipment, which provided $1.4 million in proceeds. We can borrow up to an additional $1.6 million on the line of credit through September 30, 2005. Payments on our line of credit totaled $0.3 million in 2004. In 2003, $19.7 million was provided by financing activities, primarily due to net proceeds of $18.9 million from our Series B redeemable convertible preferred stock and proceeds from a line of credit of $1.0 million, offset by line of credit payments of $0.3 million. Cash provided by financing activities in 2002 primarily reflects the $5.9 million in proceeds from the issuance of Series A Prime and Series A Double Prime redeemable convertible preferred stock.

The following table summarizes our contractual obligations and commercial commitments at December 31, 2004:

Payments Due by Period

Contractual Obligations (in thousands)	Total	2005	2006 through 2008	2009 through 2010	After 2010
License maintenance obligations	$ 985	$ 179	$ 396	$ 410	*
Short and long-term line of credit obligation	1,820	715	1,105	—	$ —
Operating lease obligations	12,187	1,473	5,989	4,050	675
Total contractual cash obligations	$14,992	$2,367	$7,490	$4,460	$ 675

* After 2010, 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 mid 2007. 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.

Funding Requirements

We have received $4.7 million as of December 31, 2004 from our collaboration with Sandoz. We did not receive payments from any collaborations from our inception through December 31, 2003. Under our Sandoz collaboration, Sandoz has agreed to fund a minimum amount of personnel and substantially all of the other ongoing development, commercialization and legal expenses incurred with

respect to our M-Enoxaparin program, subject to the right to terminate upon reaching an agreed-upon limit.

We expect to use our current cash, cash equivalents and marketable securities to continue the development of our product candidates, our discovery research programs and for other general corporate purposes. We intend to use the majority of our cash to fund:

- the approval and subsequent commercialization of near-term product candidates, including approximately $8.0 million to $10.0 million to develop M-Dalteparin through the filing of an ANDA;
- the development of analytic technology for glycoproteins including using approximately $4.0 million to $6.0 million to characterize multiple glycosylated therapeutic protein products;
- the development of improved product candidates, including using approximately $9.0 million to $12.0 million to develop M118 through Phase I and Phase IIa clinical trials and $3.0 million to $5.0 million for the initial development of pulmonary formulations of therapeutic proteins;
- the research and discovery of novel therapeutics and technologies; and
- working capital, capital expenditures and other general corporate purposes.

We expect to incur substantial costs and losses as we continue to expand our research and development activities. Our funding requirements will depend on numerous factors, including:

- the progress of development of M-Enoxaparin, M-Dalteparin, our glycoprotein program, and M118;
- the timing, receipt and amount of milestone and other payments, if any, from present and future collaborators;
- 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 costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the timing, receipt and amount of sales and royalties, if any, from our product candidates;
- the cost of manufacturing, marketing and sales activities, if any; and
- the cost of litigation, including potential patent litigation.

We do not expect to generate significant additional revenues, other than payments that we receive from our collaboration with Sandoz or other similar future collaborations, until we successfully obtain marketing approval for, and begin selling, M-Enoxaparin. We believe the key factors that will affect our internal and external sources of cash are:

- our ability to successfully develop, manufacture, obtain regulatory approval for and commercialize M-Enoxaparin;
- the success of M-Dalteparin, M118, our glycoprotein program, and other preclinical and clinical development programs;
- the receptivity of the capital markets to financings by biotechnology companies; and
- our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

If our existing resources and the proceeds of this offering are insufficient to satisfy our liquidity requirements or if we acquire or license additional technologies, products or assets that fit within our growth strategy, we may need to raise additional external funds through the sale of equity or debt securities. The sale of equity securities may result in dilution to our stockholders. Additional financing may not be available in amounts or on terms acceptable to us or at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

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 IPO, 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. Revenues from milestone payments that represent the culmination of a separate earnings process are recorded when the milestone is achieved. Contract revenues are recorded as the services are performed. When we are required to defer revenue, the period over which such revenue should be recognized is subject to estimates by management and may change over the course of the collaborative agreement.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services which have been performed on our behalf, and 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 have elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value method provided for under Statement of Financial Accounting Standard No. 123, or SFAS 123, *Accounting for Stock-Based Compensation*. In 2004, 2003 and 2002, certain grants of stock options were made at exercise prices deemed to be less than the fair value of our common stock and, as a result, we recorded deferred stock compensation expense. In the notes to our financial statements, we provide pro forma disclosures in accordance with SFAS 123. We account for transactions in which services are received from non-employees in exchange for equity instruments based on the fair value of such services received or of the equity instruments issued, whichever is more reliably measured, in accordance with SFAS 123 and the Emerging Issues Task Force, or EITF, Issue 96-18, *Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, or EITF 96-18.

Accounting for equity instruments granted or sold by us under APB 25, SFAS 123 and EITF 96-18 requires fair value estimates of the equity instrument granted or sold. If our estimates of the fair value of these equity instruments are too high or too low, our expenses may be over or under stated. Equity instruments granted or sold in exchange for the receipt of goods or services and the value of those goods or services cannot be readily estimated, as is true in connection with most stock options and warrants granted to employees and non-employees. We estimated the fair value of the equity instruments based upon consideration of factors which we deemed to be relevant at the time. Because shares of our common stock had not been publicly traded prior to our IPO, market factors historically considered in valuing stock and stock option grants included comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we were issuing, pricing of private sales of our redeemable convertible preferred stock, prior valuations of stock grants and the effect of events that had occurred between the time of such grants, economic trends, and the comparative rights and preferences of the security granted compared to the rights and preferences of our other outstanding equity.

Prior to our IPO, the fair value of our common stock was determined by our board of directors. In the absence of a public trading market for our common stock, our board of directors considered objective and subjective factors in determining the fair value of our common stock. At the time of option grants and other stock issuances, our board of directors considered the liquidation preferences, dividend rights and voting control attributable to our then-outstanding redeemable convertible preferred stock and, primarily, the likelihood of achieving a liquidity event such as an initial public offering or sale of Momenta.

Recently Issued Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), Share-Based Payment, which is a revision of Statement of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be expensed based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123(R) must be adopted in the first interim or annual period beginning after June 15, 2005, irrespective of the entity's fiscal year. Early adoption will

be permitted in periods in which financial statements have not yet been issued. The Company expects to adopt Statement 123(R) on July 1, 2005.

Statement 123(R) permits public companies to adopt its requirements using one of two methods: "modified prospective method" in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date or a "modified retrospective" method, which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company is evaluating which method of adoption it will apply for Statement 123(R).

As permitted by Statement 123, the Company currently accounts for share-based payments to employees using APB 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of Statement 123(R) fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future.

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 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, 2004, we estimate that the fair value of our investment portfolio would decline by an immaterial amount.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Momenta Pharmaceuticals, Inc.
Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Momenta Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Momenta Pharmaceuticals, Inc. ("the Company") as of December 31, 2004 and 2003, and the related statements of operations, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2004. 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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 financial position of Momenta Pharmaceuticals, Inc. at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with United States generally accepted accounting principles.

/s/ ERNST & YOUNG LLP

January 28, 2005
Boston, Massachusetts

Momenta Pharmaceuticals, Inc.

Balance Sheets

	December 31,	
	2004	2003
	(In thousands, except share and per share amounts)	
Assets		
Current assets:		
Cash and cash equivalents	$ 11,678	$ 4,613
Marketable securities	41,943	7,994
Accounts receivable	2,238	—
Unbilled collaboration revenue	2,801	2,018
Prepaid expenses and other current assets	1,456	262
Total current assets	60,116	14,887
Property and equipment, net of accumulated depreciation	2,723	1,117
Restricted cash	1,485	—
Other assets	6	80
Total assets	$ 64,330	$ 16,084
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,489	$ 804
Accrued expenses	1,611	571
Deferred revenue	147	147
Line of credit obligation	715	321
Total current liabilities	5,962	1,843
Deferred revenue, net of current portion	270	417
Line of credit obligation, net of current portion	1,105	372
Unvested restricted stock	—	6
Total liabilities	7,337	2,638
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock, $0.01 par value, issuable in series; 0 and 10,000,000 shares authorized at December 31, 2004 and 2003, respectively; none issued at December 31, 2004 and 9,117,316 issued at December 31, 2003	—	27,225
Stockholders' equity (deficit):		
Preferred stock, $.01 par value; 5,000,000 and 0 shares authorized at December 31, 2004 and 2003, respectively and no shares issued and outstanding	—	—
Common stock, $0.0001 par value; 100,000,000 and 20,000,000 shares authorized at December 31, 2004 and 2003, respectively; 25,408,944 and 4,162,805 shares issued and outstanding at December 31, 2004 and 2003, respectively	3	—
Additional paid-in capital	112,510	4,960
Deferred compensation	(3,381)	(3,034)
Due from officer	(36)	(71)
Accumulated other comprehensive loss	(159)	(6)
Accumulated deficit	(51,944)	(15,628)
Total stockholders' equity (deficit)	56,993	(13,779)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 64,330	$ 16,084

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

Momenta Pharmaceuticals, Inc.

Statements of Operations

	Year Ended December 31,		
	2004	2003	2002
	(In thousands, except per share amounts)		
Collaboration revenue	$ 7,832	$ 1,454	$ —
Operating expenses:			
Research and development*	15,722	5,347	2,174
General and administrative*	6,751	4,083	2,712
Total operating expenses	22,473	9,430	4,886
Loss from operations	(14,641)	(7,976)	(4,886)
Other income (expense):			
Interest income	605	74	17
Interest expense	(39)	(43)	—
Net loss	$(14,075)	$(7,945)	$(4,869)
Deemed dividend related to beneficial conversion feature of Series C redeemable convertible preferred stock	(20,389)	—	—
Dividends and accretion to redemption value of redeemable convertible preferred stock	(1,852)	(1,898)	(520)
Net loss attributable to common stockholders	$(36,316)	$(9,843)	$(5,389)
Basic and diluted net loss per share attributable to common stockholders	$ (2.56)	$ (5.02)	$ (5.70)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	14,177	1,961	946
* Includes stock-based compensation as follows:			
Research and development	$ 875	$ 173	$ 48
General and administrative	1,145	683	348
Total stock-based compensation	$ 2,020	$ 856	$ 396

The accompanying notes are an integral part of these financial statements

Momenta Pharmaceuticals, Inc.
STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE LOSS
In thousands

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Due from Officer	Deferred Stock Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Par Value						
Balances at December 31, 2001	250	$ 22	2,877	$—	$ 248	$—	$ —	$ —	$ (396)	$ (148)
Sale of Series A Prime Redeemable Convertible Preferred Stock, net of offering costs of $20	894	1,505								
Sale of Series A Double Prime Redeemable Convertible Preferred Stock, net of offering costs of $20	1,533	4,380								
Sale of common stock			1,071	—	1					1
Issuance of common stock for license fee			178	—	279					279
Issuance of common stock to nonemployees			31	—	—					—
Issuance of common stock pursuant to the exercise of stock options			4	—						—
Accretion of Preferred Stock to redemption value		39							(39)	(39)
Preferred Stock dividends		481							(481)	(481)
Issuance of warrant in conjunction with equipment line financing					30					30
Sale of restricted common stock					107		(107)			
Deferred stock compensation expense associated with stock options					2,109			(2,109)		
Amortization of deferred stock compensation								360		360
Compensation expense associated with options issued to nonemployees					36					36
Net loss									(4,869)	(4,869)
Balances at December 31, 2002 (carried forward)	2,677	$ 6,427	4,161	$—	$2,810	$—	$(107)	$(1,749)	$ (5,785)	$ (4,831)
Sale of Series B Redeemable Convertible Preferred Stock, net of offering costs of $100	6,440	18,900								
Issuance of common stock pursuant to the exercise of stock options			23	—	5					5
Accretion of Preferred Stock to redemption value		52							(52)	(52)
Preferred Stock dividends		1,846							(1,846)	(1,846)
Payment of officer obligation							36			36
Deferred stock compensation expense associated with stock options					1,956			(1,956)		
Amortization of deferred stock compensation								671		671
Compensation expense associated with options issued to nonemployees					184					184
Repurchase of unvested restricted stock			(21)	—						—
Vesting of restricted stock					5					5
Unrealized loss on short-term investments						(6)				(6)
Net loss									(7,945)	(7,945)
Comprehensive loss										(7,951)
Balances at December 31, 2003	9,117	$27,225	4,163	$—	$4,960	$(6)	$ (71)	$(3,034)	$(15,628)	$(13,779)

Momenta Pharmaceuticals, Inc.

STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK, STOCKHOLDERS' EQUITY (DEFICIT) AND COMPREHENSIVE LOSS (Continued)

In thousands

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Due from Officer	Deferred Stock Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Par Value						
Balances at December 31, 2003 (brought forward)	9,117	$ 27,225	4,163	$—	$ 4,960	$ (6)	$(71)	$(3,034)	$(15,628)	$(13,779)
Sale of Series C Redeemable Convertible Preferred Stock, net of offering costs of $110	2,613	20,390								
Accretion of Preferred Stock to redemption value		37							(37)	(37)
Preferred Stock dividends		1,815							(1,815)	(1,815)
Proceeds from redeemable preferred stock allocated to beneficial conversion feature					20,389					20,389
Dividend on redeemable preferred stock attributable to beneficial conversion feature									(20,389)	(20,389)
Conversion of redeemable convertible preferred stock to common stock	(11,730)	(49,467)	15,014	2	49,465					49,467
Issuance of common stock in Initial Public Offering			6,153	1	35,296					35,297
Issuance of common stock pursuant to the exercise of stock options			67	—	27					27
Payment of officer obligation							35			35
Deferred stock compensation expense associated with stock options					1,714			(1,714)		
Amortization of deferred stock compensation								1,367		1,367
Compensation expense associated with options issued to nonemployees					221					221
Compensation expense associated with accelerated vesting of employee options					432					432
Vesting of restricted stock					6					6
Cashless exercise of warrant			12	—	—					—
Unrealized loss on short-term investments						(153)				(153)
Net loss									(14,075)	(14,075)
Comprehensive loss										(14,228)
Balances at December 31, 2004	—	$ —	25,409	$ 3	$112,510	$(159)	$(36)	$(3,381)	$(51,944)	$(56,993)

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

Momenta Pharmaceuticals, Inc.

Statements of Cash Flows

	Year Ended December 31,		
	2004	2003	2002
	(In Thousands)		
Cash Flows from Operating activities:			
Net loss	$(14,075)	$(7,945)	$(4,869)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	526	252	84
Stock compensation expense	2,020	856	396
Noncash license expense	—	—	279
Noncash interest expense	11	9	—
Amortization of premium on investments	1,015	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(2,238)	—	—
Unbilled collaboration revenue	(783)	(2,018)	—
Prepaid expenses and other current assets	(1,194)	(238)	(22)
Restricted cash	(1,485)	—	—
Other Assets	74	29	(108)
Accounts payable	2,685	516	254
Accrued expenses	1,040	(33)	327
Deferred revenue	(147)	564	—
Net cash used in operating activities	(12,551)	(8,008)	(3,659)
Cash Flows from Investing activities:			
Purchases of marketable securities	(64,921)	(8,002)	—
Proceeds from maturities of marketable securities	29,804	—	—
Purchase of property and equipment	(2,132)	(502)	(950)
Net cash used in investing activities	(37,249)	(8,504)	(950)
Cash Flows from Financing activities:			
Proceeds from initial public offering of common stock, net of issuance costs	35,297	—	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	20,389	18,900	5,884
Proceeds from line of credit	1,448	1,002	—
Payments on line of credit	(331)	(289)	—
Repayment of officer obligation	35	36	—
Proceeds from issuance of common stock	27	5	15
Net cash provided by financing activities	56,865	19,654	5,899
Increase in cash and cash equivalents	7,065	3,142	1,290
Cash and cash equivalents, beginning of period	4,613	1,471	181
Cash and cash equivalents, end of period	$ 11,678	$ 4,613	$ 1,471
Supplemental Cash Flow Information:			
Cash paid for interest	$ 28	$ 34	$ —

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

1. The Company

Business

Momenta Pharmaceuticals, Inc. (the "Company") was incorporated in the state of Delaware on May 17, 2001. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the detailed structural analysis and design of complex sugars for the development of technology-enabled generic versions of complex drug products, improved versions of existing drugs, and the discovery of novel drugs and new biological processes.

Basis of Presentation

On May 10, 2004, the Company's Board of Directors authorized a 1.28-for-1 common stock split effected in the form of a common stock dividend. All common share and per share information in the accompanying financial statements has been retroactively restated to reflect such common stock split.

2. Summary of Significant Accounting Policies

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, and U.S. government 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 debt securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive loss and reported as a separate component of stockholders' equity (deficit). 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. The cost of securities sold is based on the specific identification method. Interest earned on short-term investments 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 equivalents and marketable securities. The Company has established guidelines relating to diversification and maturities that allows the Company to manage risk.

2. Summary of Significant Accounting Policies (Continued)

Fair Value of Financial Instruments

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

Accounts Receivable

Accounts receivable represents an amount owed from one collaborative partner at December 31, 2004. The Company has not recorded any bad debt write-offs and it monitors its receivables closely to help ensure timely payment.

Property and Equipment

Property and equipment is 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. On disposal, the related cost and accumulated depreciation or amortization are 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. 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 and equipment and other long-lived assets when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of Statement of Financial Account Standards ("SFAS") No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144). SFAS No. 144 further refines the requirements of SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of*, 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 No. 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, 2004.

Revenue Recognition

Revenues associated with the Company's collaboration with Sandoz include an initial payment, reimbursement of development services and expenses, and potential future milestones and royalties. The initial payment represented reimbursement of specific development costs incurred prior to the date of the collaboration. Amounts earned under the collaboration agreement are not refundable if the research or development is unsuccessful. To date, the Company has not earned any milestones or royalties.

2. Summary of Significant Accounting Policies (Continued)

The Company uses revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements*, as revised by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force ("EITF") Issue 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into collaboration revenue in the statement of operations over the term of the performance obligation. Revenues from research and development services and expenses are recognized in the period the services are performed and the reimbursable costs are incurred.

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.

Stock-Based Compensation

The Company has elected to account for its stock-based compensation plans following Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations, rather than the alternative fair value accounting provided under SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). In accordance with EITF 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Connection with Selling Goods or Services* (EITF 96-18), the Company records compensation expense equal to the fair value of options granted to non-employees over the vesting period, which is generally the period of service.

Pro forma information regarding net loss is required by SFAS 123 as if the Company had accounted for its stock-based awards to employees under the fair value method of SFAS 123. The fair value of the Company's stock options used to compute pro forma net loss is the estimated value at the grant date using the Black-Scholes option-pricing model with the following weighted-average assumptions for each of the three years in the period ended December 31, 2004:

	2004	2003	2002
Risk-free interest rate	3.7%	3.5%	4.5%
Expected volatility	80%	80%	80%
Expected lives	7 years	7 years	7 years
Expected dividend	—	—	—

The per-share, weighted-average grant date fair value of options granted during the years ended December 31, 2004, 2003 and 2002 were $4.35, $3.53 and $1.45, respectively.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized over the vesting period of the options. Had compensation expense for the Company's stock-based compensation plans been determined based on the fair value at the grant dates for awards under those

2. Summary of Significant Accounting Policies (Continued)

plans consistent with the method of SFAS 123, the Company's net loss for fiscal 2004, 2003 and 2002 would have been as follows:

	2004	2003	2002
	(in thousands, except per share data)		
Net loss attributable to common stockholders as reported	$(36,316)	$(9,843)	$(5,389)
Add: Stock-based employee compensation expense included in reported net loss	1,799	280	53
Deduct: Stock-based employee compensation expense determined under fair value based method	(1,148)	(280)	(35)
SFAS 123 Pro forma net loss	$(35,665)	$(9,843)	$(5,371)
Basic and diluted net loss per share			
As reported	$ (2.56)	$ (5.02)	$ (5.70)
SFAS 123 Pro forma	$ (2.52)	$ (5.02)	$ (5.68)

Redeemable Convertible Preferred Stock

In connection with the closing of the Company's initial public offering in the second quarter of 2004, all shares of redeemable convertible preferred stock were converted to common stock. Prior to our initial public offering, the carrying value of redeemable convertible preferred stock was increased by periodic accretions so that the carrying amount would equal the redemption value at the redemption date. These accretions were effected through charges against accumulated deficit. The holders of redeemable convertible preferred stock were entitled to dividends at 10% per annum through their redemption date, payable only upon redemption.

Income Taxes

The Company accounts for income taxes under SFAS No. 109, *Accounting for Income Taxes*. 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.

Comprehensive Loss

The Company reports comprehensive loss in accordance with SFAS No. 130, *Reporting Comprehensive Income* (SFAS 130). SFAS 130 establishes rules for the reporting and display of comprehensive loss and its components. Accumulated other comprehensive loss as of December 31, 2004 and 2003 consists entirely of unrealized losses on available-for-sale securities. Comprehensive loss for the year ended December 31, 2002 equaled net loss.

Net Loss Per Share

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings per Share* (SFAS No. 128). Under the provisions of SFAS 128, basic net loss per common share is computed by

2. Summary of Significant Accounting Policies (Continued)

dividing net loss by the weighted-average number of common shares outstanding. 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. Common equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock, shares issuable upon the exercise of stock options and upon the exercise of warrants. The Company has excluded the impact of all convertible preferred stock, stock options and shares of common stock subject to repurchase from the calculation of historical diluted net loss per common share because all such securities are antidilutive for all periods presented. The total number of shares excluded from the calculations of historical diluted net loss per share was 1,334,575, 14,332,014 and 6,622,196 for the years ended December 31, 2004, 2003 and 2002, respectively.

Segment Reporting

The Company has adopted SFAS No. 131, *Disclosure About Segments of an Enterprise and Related Information*, which requires companies to report selected information about operating segments, as well as enterprisewide 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 our revenues through December 31, 2004 have come from one collaborative partner.

Recently Issued Accounting Standards

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), Share-Based Payment, which is a revision of Statement of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be expensed based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123(R) must be adopted in the first interim or annual period beginning after June 15, 2005, irrespective of the entity's fiscal year. Early adoption will be permitted in periods in which financial statements have not yet been issued. The Company expects to adopt Statement 123(R) on July 1, 2005.

Statement 123(R) permits public companies to adopt its requirements using one of two methods: "modified prospective method" in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date or a "modified retrospective" method, which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company is evaluating which method of adoption it will apply for Statement 123(R).

2. Summary of Significant Accounting Policies (Continued)

As permitted by Statement 123, the Company currently accounts for share-based payments to employees using APB 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of Statement 123(R) fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net loss per share earlier in this footnote.

3. Collaboration and License Agreements

Sandoz

In November 2003, the Company entered into a collaboration and license agreement with Sandoz to jointly develop and commercialize M-Enoxaparin, a generic version of Lovenox, a low molecular weight heparin. Under the terms of this agreement, the Company and Sandoz agree to exclusively work with each other to develop and commercialize M-Enoxaparin for medical indications within the United States.

Under this collaboration, Sandoz pays the Company for full-time equivalent scientific, technical and/or management services. 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 in the United States, share profits with us; 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 enoxaparin. As of December 31, 2004, the Company recorded a total of $9.3 million as collaboration revenue under this agreement, including $0.2 million in amortization of an initial payment of $0.6 million (for reimbursement of development costs the Company incurred prior to signing the agreement) and $9.1 million for personnel and other reimburseable development costs. The initial payment was deferred and is being amortized into revenue over the development period, estimated to be four years. Sandoz may also make additional payments to the Company up to an aggregate of $55.0 million, upon our achievement of certain milestones. If the development and commercialization costs and legal expenses, in the aggregate, exceed a specified amount, Sandoz is permitted to offset a portion of the excess against the profit-sharing amounts, the royalties and certain milestone payments.

The Company is in discussions with Sandoz regarding an exclusive license to develop and commercialize injectable enoxaparin outside of the United States. Sandoz may exercise a right of first negotiation to work with the Company on the research, development, manufacturing or commercialization inside and/or outside the United States, of a generic version of Fragmin, M118, and/or enoxaparin administered by any route of delivery other than injection or certain improved forms of enoxaparin.

3. Collaboration and License Agreements (Continued)

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 $117,500, $57,500 and $90,000 as research and development expense related to M.I.T. license and maintenance fees in the years ended December 31, 2004, 2003 and 2002 respectively.

Pursuant to the license agreement, in 2001 the Company issued an aggregate of 197,356 shares of common stock to M.I.T. and certain of its affiliates (the "University Stockholders"). In connection with the issuance of common stock, the Company recorded $15,000 in research and development expense during 2001 representing the fair market value of the common stock at the time of issuance. Subject to certain conditions, the University Stockholders were entitled to additional shares of common stock, such that the University Stockholders' ownership of the Company's outstanding common stock, in the aggregate, would not be less than 5% on a fully-diluted basis. Such additional shares were to be issued on the date upon which the Company received a total of $5.0 million in cash in exchange for the Company's capital stock. On April 16, 2002, the Company reached such $5.0 million equity threshold and distributed an aggregate of 177,632 additional shares of common stock to the University Stockholders. Upon such distribution, all rights to further issuances were terminated. In connection with the issuance of common stock, the Company recorded $279,000 in research and development expense during the year ended December 31, 2002 representing the fair market value of the common stock at the time of issuance.

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 collaboration and license agreement and agrees to assume the Company's rights and obligations to M.I.T.

The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory

In November 2002, the Company entered into an agreement with The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory ("Lawrence Berkeley National Lab") under which the Company licensed certain patents and applications covering the metabolic synthesis of sugars and glycoconjugates and were granted an exclusive license, with the right to grant sublicenses, for the synthesis, production or modification of sugars and glycoconjugates in or

3. Collaboration and License Agreements (Continued)

on biological molecules for purposes of researching, developing and commercializing products, services and processes for all human therapeutic applications, excluding the sale of research reagents. This agreement was subsequently amended as the Company elected to retain the license under the broad field.

In return for these initial license rights, the Company paid Lawrence Berkeley National Lab a license issue fee, and it pays royalties, subject to annual minimum amounts. The Company will also pay a fee in 2005 related to the election to retain the broad field. If the Company sublicenses its rights, the Company also pays a percentage of the fees received from its sublicensees. The Company is also responsible for patent prosecution and maintenance costs. The Company recorded $10,000, $30,000 and $20,000 as research and development expense related to license fees in the years ended December 31, 2004, 2003 and 2002 respectively.

Siegfried (U.S.A.), Inc. and Siegfried Ltd.

In 2003, the Company entered into a process development and production agreement, as amended in 2004 and 2005, with Siegfried (U.S.A), Inc. and Siegfried Ltd. ("Siegfried") under which the Company provided to Siegfried its existing laboratory-scale processes and analytical methods for the production of enoxaparin. Siegfried's responsibility is to further develop the processes and, once the Company approves of such processes, to manufacture the active pharmaceutical ingredient enoxaparin sodium for use in stability, preclinical, and clinical studies and for other development purposes. The Company recorded $0.8 million and $0.1 million as research and development expense for services from Siegfried during the years ended December 31, 2004 and 2003, respectively.

4. Financial Instruments

The following is a summary of cash, cash equivalents, and marketable securities as of December 31, 2004 and 2003 (in thousands):

December 31, 2004	Cost	Gross Unrealized Losses	Fair Value
Cash	$ 2,316	$ —	$ 2,316
Money market funds	6,365	—	6,365
Corporate debt securities			
Due in one year or less	37,144	(98)	37,046
Due in one to two years	7,955	(61)	7,894
Total corporate debt securities	45,099	(159)	44,940
	$53,780	$(159)	$53,621
Reported as:			
Cash and cash equivalents	$11,678	$ —	$11,678
Marketable securities	42,102	(159)	41,943
	$53,780	$(159)	$53,621

December 31, 2003	Cost	Gross Unrealized Losses	Fair Value
Cash	$ 261	$—	$ 261
Money market funds	1,846	—	1,846
Corporate debt securities			
Due in one year or less	10,506	(6)	10,500
	$12,613	$(6)	$12,607
Reported as:			
Cash and cash equivalents	$ 4,614	$(1)	$ 4,613
Marketable securities	7,999	(5)	7,994
	$12,613	$(6)	$12,607

The aggregate fair value of corporate debt securities in an unrealized loss position for less than a year was approximately $41.0 million and $9.7 million at December 31, 2004 and 2003, respectively. There were no investments at December 31, 2004 or 2003 that were in an unrealized position for greater than one year. 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. Investments in an unrealized loss position were caused by fluctuations in interest rates. The Company reviewed its investments with unrealized losses and has concluded that no other-than-temporary impairment existed at December 31, 2004 and 2003. The Company had no realized gains or losses during the years ended December 31, 2004, 2003 or 2002.

5. Property and Equipment

At December 31, 2004 and 2003, property and equipment, net consists of the following (in thousands):

	2004	2003
Computer equipment	$ 307	$ 140
Software	156	—
Office furniture and equipment	314	14
Laboratory equipment	2,336	1,083
Leasehold improvements	473	217
Less: accumulated depreciation	(863)	(337)
	$2,723	$1,117

Depreciation expense amounted to $526,000, $252,000 and $84,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

6. 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.

7. Accrued Expenses

At December 31, 2004 and 2003, accrued expenses consisted of the following (in thousands):

	2004	2003
Accrued compensation	$ 629	$210
Accrued contracted research costs	460	103
Accrued license fees	—	59
Accrued professional fees	343	91
Other	179	108
	$1,611	$571

8. Redeemable Convertible Preferred Stock

Series C Preferred Stock

In February 2004, the Company sold 2,612,696 shares of Series C redeemable convertible preferred stock for net proceeds of $20.4 million. These shares contained a beneficial conversion feature based on the fair value of the Company's common stock at the date of such sale compared to the Series C redeemable convertible preferred stock share price. For financial accounting purposes, the total value of the beneficial conversion feature of approximately $20.4 million was recognized as a dividend in the first quarter of 2004.

8. Redeemable Convertible Preferred Stock (Continued)

Conversion

On June 25, 2004, the Company completed an initial public offering of its common stock. In connection with the closing of its initial public offering, each share of the Company's redeemable convertible preferred stock was converted into that number of shares of common stock that resulted from dividing $1.00, $1.7067, $2.87, $2.95 and $7.8463 for the Series A Preferred, the Series A Prime Preferred, the Series A Double Prime Preferred, the Series B Preferred and the Series C Preferred, respectively, by the then-applicable conversion price for each series of preferred stock in effect at the time of conversion which was $0.78, $1.33, $2.24, $2.31 and $6.13 for the Series A Preferred, the Series A Prime Preferred, the Series A Double Prime, the Series B Preferred and the Series C Preferred, respectively. In the aggregate, 15,014,415 shares of common stock were issued in connection with such conversion.

The carrying value of redeemable convertible preferred stock, reflecting dividends and accretion to redemption value, is summarized below (in thousands):

	December 31, 2003
Series A: 250 shares authorized, issued and outstanding	$ 140
Series A Prime: 893 shares authorized, issued and outstanding	1,806
Series A Double Prime: 1,546 authorized, 1,533 shares issued and outstanding	5,139
Series B: 6,441 shares authorized, issued and outstanding	20,140
	$27,225

9. Warrants

In 2002, in connection with a bank line of credit agreement, the Company granted a warrant to purchase 12,500 shares of Series A Double Prime Redeemable Convertible Preferred Stock at an exercise price of $2.87 per share. The fair value of the warrant was estimated to be $29,875, which was recorded as additional paid-in capital and as prepaid interest at December 31, 2002. This prepaid interest amount is being amortized as interest expense over the 36-month term of the line of credit. On November 30, 2004, the warrant was exercised and the Company issued 11,569 shares of common stock in connection with a cashless exercise.

10. 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.

Shares of common stock reserved for future issuance are as follows (in thousands):

	December 31, 2004
Common stock:	
Shares available for grant under stock option plans	3,757
Exercise of outstanding options	1,335
Shares available for grant under employee stock purchase plan	525
	5,617

On May 10, 2004, the Company's Board of Directors authorized a 1.28-for-1 common stock split effected in the form of a common stock dividend. All common share and per share information in the accompanying financial statements has been retroactively restated to reflect such common stock split.

On June 25, 2004, the Company successfully completed an initial public offering of its common stock. The initial public offering consisted of the sale of 5,350,000 shares of common stock at a price of $6.50 per share. As part of the offering, the Company granted to the underwriters an option to purchase an additional 802,500 shares within 30 days of the initial public offering to cover over-allotments. This option was exercised in full in connection with the closing of the initial public offering. Net proceeds from the initial public offering after deducting underwriters' discounts and expenses were $35.3 million.

Share Restriction Agreements

On June 13, 2001, the Company entered into Restricted Stock Purchase Agreements with certain employees and non-employees to purchase an aggregate of 2,680,003 shares of common stock. Each Restricted Stock Purchase Agreement provides for the repurchase of common stock held by these individuals and entities by the Company at a rate of $0.0001 per share, the original purchase price, adjustable for certain dilutive events, until the shares vest. The repurchase provisions lapse over a 45-month period commencing on September 13, 2001, provided that each individual and entity subject to such agreements continues service with the Company.

During 2002, the Company entered into Restricted Stock Purchase Agreements with two officers and a non-employee to purchase an aggregate of 1,101,870 shares of common stock. Pursuant to one of the Restricted Stock Purchase Agreements, 980,859 shares of common stock were sold to an officer for $106,662. The purchase price is payable ratably over approximately three years and is included in stockholders' equity (deficit) as Due from Officer. At December 31, 2004, each Restricted Stock Purchase Agreement provides for the repurchase of common stock held by these individuals and entities by the Company at a price equal to the original price paid, adjustable for certain dilutive events, until the shares vest. The repurchase provisions generally lapse over a three-to four-year period provided that each individual and entity subject to such agreements continues service with the Company.

10. Common Stock (Continued)

At December 31, 2004 and 2003, there were 667,733 and 1,605,502 shares of unvested restricted common stock outstanding, respectively.

11. Stock Option Plans

The Company's 2002 Stock Incentive Plan, as amended, provides for the granting of stock options and restricted stock to employees, officers, directors, consultants and advisors to purchase the Company's Common Stock. As of December 31, 2004, the Company was authorized to issue options to purchase 1,237,377 shares of Common Stock under the 2002 Stock Incentive Plan. Options granted under the 2002 Stock Incentive Plan may be Incentive Stock Options or Nonstatutory Stock Options under the applicable provisions of the Internal Revenue Code. Since the effective date of the 2004 Stock Incentive Plan described below, the Company will no longer grant options under the 2002 Stock Incentive Plan. Any authorized and ungranted shares, and unvested shares granted that are returned to the Company as a result of terminations will subsequently lapse.

On March 8, 2004, the Company's 2004 Stock Incentive Plan (the "Incentive Plan") was adopted by the Board of Directors and was approved by the Company's stockholders on June 10, 2004. Pursuant to the terms of the Incentive Plan, the Company is authorized to issue up to 3,948,785 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. The Company's Board of Directors elected not to increase the number of authorized shares related to the Incentive Plan for 2005.

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. Non-statutory Stock Options may be granted to employees, officers, directors, consultants and advisors. Incentive Stock Options generally vest either upon grant or ratably over four years. Non-statutory Stock Options granted have varying vesting schedules. The options generally expire ten years after the date of grant.

11. Stock Option Plans (Continued)

The following table summarizes all stock plan activity (in thousands, except per share data):

	Shares Outstanding	Price Per Share	Weighted-Average Exercise Price
Balance at December 31, 2001	19	$ 0.08	$0.08
Shares granted	469	0.23	0.23
Shares exercised	(4)	0.08	0.08
Shares canceled	(51)	0.23	0.23
Balance at December 31, 2002	433	0.08–0.23	0.22
Shares granted	621	0.23–0.60	0.34
Shares exercised	(23)	0.08–0.23	0.22
Balance at December 31, 2003	1,031	0.08–0.60	0.29
Shares granted	392	.60–8.65	5.62
Shares exercised	(67)	0.23–4.91	0.41
Shares cancelled	(21)	0.23–4.91	0.49
Balance at December 31, 2004	1,335	$0.08–8.65	$1.85

The following table summarizes information about options outstanding at December 31, 2004 (in thousands, except per share data):

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (In years)	Number of Shares	Weighted Average Exercise Price
$ 0.08	14	$0.08	7.0	9	$0.08
0.23–.231	757	0.23	8.1	359	0.23
0.60–4.91	372	2.03	9.1	69	1.39
6.50–8.65	192	8.02	9.5	4	8.14
	1,335	$1.85	8.5	441	$0.48

During 2004, 2003 and 2002, the Company granted 204,285, 621,155, and 436,651 options, respectively, to employees at exercise prices that were deemed to be below the fair value of the Company's common stock. The weighted average exercise price of these options was $3.39, $0.34 and $0.22 for 2004, 2003 and 2002, respectively.

Stock-Based Compensation

As discussed in Note 2, the Company applies APB 25 and related interpretations in accounting for stock options granted under its stock option plans. The Company recorded $1.7 million, $2.0 million and $0.5 million during the years ending December 31, 2004, 2003 and 2002, respectively, in deferred compensation for employee stock options granted at exercise prices deemed to be below the fair value of common stock. In addition, for the year ended December 31, 2002 the Company recorded $1.6 million in deferred compensation for restricted stock granted to employees at purchase prices deemed to be below the fair value of common stock.

11. Stock Option Plans (Continued)

The Company amortizes the deferred stock-based compensation of employee options and restricted stock to compensation expense based on the straight-line method over the vesting periods of the applicable stock options and restricted stock, generally four years. Compensation expense of $1.4 million, $0.7 million and $0.4 million was recognized for employee options and restricted stock, net of forfeitures during the years ending December 31, 2004, 2003 and 2002, respectively.

During 2004, the Company recorded non-cash compensation expense of $0.4 million related to the accelerated vesting of stock options for an officer in connection with a termination agreement.

Stock Options to Consultants

As of December 31, 2004, the Company had granted options to purchase 86,600 shares of common stock to consultants, 9,598 of which were exercised, none of which were subject to repurchase, and 37,067 of which were unvested. These options were granted in exchange for consulting services to be rendered and vest over periods of up to four years. The Company recorded charges to operations for stock options granted to consultants using the graded-vesting method of $221,000, $184,000 and $36,000 during the years ending December 31, 2004, 2003 and 2002, respectively.

The unvested shares held by consultants have been and will be revalued using the Company's estimate of fair value at each balance sheet date pursuant to EITF 96-18.

12. Income Taxes

A reconciliation of federal statutory income tax provision to the Company's actual provision for the years ended December 31, 2004, 2003 and 2002 is as follows:

	2004	2003	2002
Benefit at federal statutory tax rate	$(4,785)	$(2,701)	$(1,569)
Unbenefited operating losses	4,747	2,668	1,559
Other	38	33	10
Income tax provision	$ —	$ —	$ —

12. Income Taxes (Continued)

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,	
	2004	2003
Deferred tax assets:		
Federal and state net operating losses	$ 9,267	$4,430
Research credits	858	254
Deferred compensation	1,364	526
Deferred revenue	168	227
Accrued expenses	100	—
Total deferred tax assets	11,757	5,437
Deferred tax liabilities:		
Depreciation	(128)	(58)
Total deferred tax liabilities	(128)	(58)
Valuation allowance	(11,629)	(5,379)
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 $6.3 million and $3.3 million for the years ended December 31, 2004 and 2003, respectively.

As of December 31, 2004, the Company had net operating loss carryforwards of $23.0 million to offset future federal and state taxable income. The Company also has federal and state research and development tax credits of approximately $0.6 million and $0.4 million, respectively, as of December 31, 2004. The net operating loss carryforwards and federal research credits expire at various times through 2024.

Utilization of the Company's net operating loss may be subject to substantial annual limitation due to the ownership change limitations provided by Internal Revenue Code (IRC) Sections 382 and 383 and similar state provisions. Such an annual limitation could result in the expiration of net operating losses and/or tax credits before utilization.

13. Commitments and Contingencies

The Company leases office space and equipment under various operating lease agreements. Rent expense under operating leases amounted to $869,000, $329,000 and $217,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

In September 2004, the Company entered into a sublease agreement with Vertex Pharmaceuticals, as sublandlord, to sublease 20,000 square feet for an initial period of approximately six months, and 45,000 square feet of office and laboratory space, thereafter. The term of the sublease is 80 months commencing on September 15, 2004. The Company has an option to extend the sublease for one

13. Commitments and Contingencies (Continued)

additional term of 48 months expiring on April 30, 2015, or on such other earlier date as provided in accordance with the sublease agreement.

At December 31, 2004, future minimum payments under noncancelable leases with terms of one year or more are as follows (in thousands):

2005	$ 1,473
2006	1,938
2007	2,026
2008	2,025
2009	2,025
2010 and beyond	2,700
Total minimum lease payments	$12,187

In connection with license arrangements signed during 2002 and 2001 and related amendments in 2003 and 2004 with the research universities discussed in Note 3, the Company has certain annual fixed obligations to pay these institutions fees for the technology licensed. At December 31, 2004, financial obligations under these agreements for each year in the next five years range from $0.1 million to $0.2 million.

After 2009, the annual obligations, which extend indefinitely are approximately $0.2 million per year. The Company may terminate the agreements at any time without obligation for future payments. Annual payments may be applied towards royalties payable to the licensors for that year for product sales, sublicensing of the patent rights or joint development revenue.

Companies that seek to market generic versions of branded products can be sued for infringing patents that purportedly cover such products and/or methods of using such products if the proposed marketing is to occur before such patents expire. Although the Company is not currently engaged in any actual or threatened material litigation, the Company believes that its product development plans will likely cause such litigation in the future. The accompanying financials do not include any provision or reserves for such potential litigation.

14. Line of Credit

In December 2002, the Company entered into an equipment line of credit with Silicon Valley Bank (the "Bank"), which provided for the Company to draw up to $1.2 million through March 31, 2003. Borrowings under the line bear interest at a rate between 5.0% and prime plus 0.25% and are payable over a 36-month period from the cash drawn date. The line of credit includes a provision that any material adverse change in the Company or its business may be considered an event of default. There have been no events of default. As of December 31, 2004, the Company had drawn $1.0 million against the line of credit. In December 2004, the Company entered into a Loan Modification Agreement (the "Loan Modification Agreement") with the Bank to amend selected terms and conditions of the Security Agreement of December 2002 by and between the Company and the Bank (the "Original Credit Facility"). Under the Loan Modification Agreement, the Company and the Bank agreed to amend the Original Credit Facility to, among other things, conform certain provisions of the Original Credit Facility to the Loan Agreement (see below), including the grant of security interest. The Company's ability to draw down any amounts under the Original Credit Facility expired on May 30,

14. Line of Credit (Continued)

2003, which term was not extended under the Loan Modification Agreement. As of December 31, 2004, the Company had approximately $382,400 in borrowings outstanding under the Original Credit Facility, as amended by the Loan Modification Agreement.

In December 2004, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with the Bank. Under the terms of the Loan Agreement, the Company may borrow up to an aggregate of $3.0 million through September 30, 2005 solely for reimbursement of purchases of Eligible Equipment, as defined under the Loan Agreement. The Company is not obligated to draw down any amounts under the Loan Agreement and any borrowings shall 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 shall be 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, 2004, the Company had approximately $1.45 million in borrowings outstanding under the Loan Agreement.

15. 401(k) Plan and Employee Stock Purchase Plan

In 2003, the Company established 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 amount contributed in 2004 by the Company was immaterial.

In March 2004, the Company's 2004 Employee Stock Purchase Plan (the "Purchase Plan") was adopted by the Company's Board of Directors and subsequently approved by the Company's stockholders. The Purchase Plan became effective on June 25, 2004, the effective date of our initial public offering. The Purchase Plan allows employees to purchase stock at a price equal to 85% of the lower of the closing price of the Company's common stock on the first day or the last day (January 31, 2005) for the first plan period. Subsequent periods will be for the 12 months ended January 31.

16. Related Party Transactions

Parivid, LLC, a company that provides data integration and analysis services to the Company, is considered to be a related party as a Co-Founder and member of the Company's Board of Directors is the brother of the chief technical officer of Parivid. For the year ending December 31, 2004, the Company recorded $1.0 million in research and development expense related to work performed by Parivid. The Company had no Parivid expenses in 2003 and 2002. At December 31, 2004, the Company had an outstanding balance of $0.1 million to be paid to Parivid.

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

	Quarter Ended			
	March 31	June 30	September 30	December 31
2004				
Collaborative revenues	$ 1,037	$ 2,115	$ 1,843	$ 2,838
Net loss	(2,582)	(2,890)	(4,270)	(4,333)
Net loss attributable to common stockholders	(23,788)	(3,924)	(4,270)	(4,333)
Basic and diluted net loss per common share attributable to common stockholders	$ (9.04)	$ (0.79)	$ (0.18)	$ (0.18)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	2,631	4,985	24,309	24,559
2003				
Collaborative revenues	—	—	—	$ 1,454
Net loss	$ (1,498)	$(1,801)	$(2,380)	(2,266)
Net loss attributable to common stockholders	(1,662)	(2,143)	(3,076)	(2,962)
Basic and diluted net loss per common share attributable to common stockholders	(1.13)	(1.14)	(1.45)	(1.25)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	1,474	1,881	2,117	2,361

Per common share amounts for the quarters and full years have been calculated separately. Accordingly, quarterly amounts do 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 are 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

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, 2004. 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. 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 applied 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, 2004, our disclosure controls and procedures were effective at the reasonable assurance level.

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 December 31, 2004 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 AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information relating to our directors, nominees for election as directors and executive officers under the headings "Election of Directors", "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our definitive proxy statement for the 2005 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 National Market by filing such amendment or waiver with the Securities and Exchange Commission and by posting it on our website.

Item 11. EXECUTIVE COMPENSATION

The discussion under the heading "Executive Compensation" in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement. The information specified in Item 402(k) and (l) of Regulation S-K and set forth in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is not incorporated by reference.

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 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The discussion under the heading "Certain Relationships and Related Transactions" in our definitive proxy statement for the 2005 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 "Independent Auditors Fees and Other Matters" in our definitive proxy statement for the 2005 Annual Meeting of Stockholders is incorporated herein by reference to such proxy statement.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. Financial Statements:

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

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

SIGNATURES

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

MOMENTA PHARMACEUTICALS, INC.

Date: March 31, 2005

By: /s/ ALAN L. CRANE
Alan L. Crane
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/ ALAN L. CRANE Alan L. Crane	Chairperson of the Board, President and Chief Executive Officer; Director (Principal Executive Officer)	March 31, 2005
/s/ RICHARD P. SHEA Richard P. Shea	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2005
/s/ PETER BARRETT Peter Barrett	Director	March 31, 2005
/s/ JOHN K. CLARKE John K. Clarke	Director	March 31, 2005
/s/ MARSHA H. FANUCCI Marsha H. Fanucci	Director	March 31, 2005
/s/ PETER BARTON HUTT Peter Barton Hutt	Director	March 31, 2005
/s/ ROBERT S. LANGER, Jr. Robert S. Langer, Jr.	Director	March 31, 2005

Signature	Title	Date
/s/ STEPHEN T. REEDERS Stephen T. Reeders	Director	March 31, 2005
/s/ RAM SASISEKHARAN Ram Sasisekharan	Director	March 31, 2005
/s/ BENNETT M. SHAPIRO Bennett M. Shapiro	Director	March 31, 2005
/s/ CHRISTOPH H. WESTPHAL Christoph H. Westphal	Director	March 31, 2005