MOMENTA PHARMACEUTICALS INC

FORM S-1/A
(Securities Registration Statement)

Filed 5/21/2004

Address	43 MOULTON STREET
	CAMBRIDGE, Massachusetts 02138
Telephone	617-491-9700
CIK	0001235010
Fiscal Year	12/31

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As filed with the Securities and Exchange Commission on May 21, 2004.

Registration No. 333-113522

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

Amendment No. 3
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Delaware	**2836**	**04-3561634**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

43 Moulton Street
Cambridge, MA 02138
(617) 491-9700
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Alan L. Crane
Chairman of the Board, President and Chief Executive Officer
Momenta Pharmaceuticals, Inc.
43 Moulton Street
Cambridge, MA 02138
(617) 491-9700
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Steven D. Singer, Esq.
Philip P. Rossetti, Esq.
Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

Jonathan L. Kravetz, Esq.
Darin P. Smith, Esq.
Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
One Financial Center
Boston, Massachusetts 02111
(617) 542-6000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date hereof.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration

statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. ☐

If delivery of the Prospectus is expected to be made pursuant to Rule 434, please check the following box. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Subject to completion, dated May 21, 2004

5,350,000 Shares

Common Stock

Momenta Pharmaceuticals, Inc. is offering 5,350,000 shares of common stock. This is our initial public offering, and no public market currently exists for our shares. We anticipate that the initial public offering price will be between $13.00 and $15.00 per share. After the offering, the market price for our shares may be outside this range.

We have applied to have our common stock approved for quotation on the NASDAQ National Market under the symbol "MNTA."

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 7.

	Per Share	Total
Offering price	$	$
Discounts and commissions to underwriters	$	$
Offering proceeds to Momenta Pharmaceuticals, Inc. before expenses	$	$

We have granted the underwriters the right to purchase up to 802,500 additional shares of common stock to cover any over-allotments. The underwriters can exercise this right at any time within 30 days after the offering. The underwriters expect to deliver the shares of common stock to investors on or about , 2004.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is accurate or complete. Any representation to the contrary is a criminal offense.

SG Cowen & Co. **Banc of America Securities LLC**

ThinkEquity Partners

CIBC World Markets

, 2004

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SUMMARY

This summary highlights information contained elsewhere in this prospectus that we believe is most important to understanding how our business is currently being conducted. You should read the entire prospectus carefully, including the "Risk Factors" section and the financial statements and related notes included in this prospectus, before making an investment decision.

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, or analyze the molecular structure of, sugars, to create generic versions of complex sugar-based drugs, or technology-enabled generic products. Through detailed analysis of the molecular structure of complex sugars, our technology provides a more complete understanding of the roles that sugars play in cellular function, disease and drug action. Based on our understanding of complex sugars, we have developed a diversified pipeline of novel discovery and development candidates and near-term product opportunities.

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox® (enoxaparin), a low molecular weight heparin, or LMWH, used to prevent and treat deep vein thrombosis, or DVT, and treat acute coronary syndromes, or ACS. Aventis SA, or Aventis, reported worldwide sales of Lovenox of approximately $1.9 billion in 2003, and analysts project sales to exceed $3.0 billion in 2008. We expect to file an Abbreviated New Drug Application, or ANDA, or other regulatory application as determined by the United States Food and Drug Administration, or FDA, for M-Enoxaparin in the next 12 months. In addition, we intend to develop a technology-enabled generic version of Fragmin® (dalteparin), another LMWH. Our novel development opportunities include: M118, which is a LMWH to treat patients with ACS that has been designed by selecting specific sugar sequences with beneficial biological activity; a technology designed to use specific sugar sequences to improve the non-invasive delivery of therapeutic proteins; and capabilities that are designed to enable engineering of complex sugars on therapeutic proteins to improve the efficacy, reduce side effects and modify the dosage of protein drugs. Our drug discovery program, which is focused initially in oncology, is based upon our understanding of sugar biology. We believe that we will be able to use this understanding to develop sugar-based drugs and identify new biological mechanisms that can be targeted with small molecule or antibody drugs.

Background on Sugars

Sugars, together with DNA and proteins, are the critical molecules that regulate biological processes and pathways in the human body. Due to the complex molecular structures of sugars and the lack of sophisticated analytical tools and methods required to examine the minute quantities of sugars that occur in nature, sugars have not been well defined or analyzed. Without being able to identify specific structures, it is not presently possible to monitor how these sugars act in biological organisms. As a consequence, the development of sugar-based drugs to date has been through more of a "trial-and-error" approach. Because of the density of information contained in complex sugars relative to DNA and proteins and the lack of sophisticated tools to sequence such sugars, development of therapeutics based on sugars has been difficult. We believe understanding the structure, specific function and manner in which complex sugars affect critical biological processes and existing therapeutics will provide significant commercial opportunities for drug discovery and development.

Our Technology Solution

Our technology enables rapid, precise and comprehensive sequencing and identification of the distinct chemical structures of a mixture, or characterization, of complex sugars and allows us to correlate specific sugar sequences with biological activity. With proprietary enzymes and reagents, improvements to established analytical techniques and patent-protected mathematical methods, our technology allows us to specifically identify the detailed sequences and the complete chemical structure of complex sugars, not simply the basic underlying backbone of the sugar chain. We intend to utilize our technology to develop generic versions of complex drugs, enhance existing therapeutics, engineer novel drugs and identify the roles sugars play in regulating biological processes to facilitate the discovery of new sugar-based, small molecule and antibody drugs, as well as the development of diagnostic tests to diagnose disease and determine disease severity.

Our Product Pipeline

Near-Term Product Opportunities

M-Enoxaparin. Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox. Lovenox is distributed worldwide by Aventis, and is the most widely-prescribed LMWH in the world. In 2003, Aventis reported worldwide sales of Lovenox of approximately $1.9 billion. We have formed a collaboration with Sandoz N.V., and Sandoz Inc., collectively Sandoz, an affiliate of Novartis AG, to jointly develop, manufacture and commercialize a generic version of Lovenox. We intend to file our regulatory application with the FDA in the next 12 months for this product.

Lovenox is a heterogeneous mixture of complex sugar chains that has not been adequately analyzed to date. Under FDA guidelines, any regulatory application for a generic product, such as a generic version of Lovenox, must demonstrate that it is therapeutically equivalent to the branded drug, meaning, among other things, that it has the same active ingredients as the branded version and is bioequivalent. Our ability to sequence and analyze complex sugar mixtures has allowed us to study the many sugar structures in Lovenox that contribute to its overall biological activity and develop a process for making a generic version of Lovenox we believe will meet the FDA requirements for an ANDA approval, including therapeutic equivalence. If we are not able to demonstrate therapeutic equivalence for our generic versions of complex drugs, such as LMWHs, our development and commercialization efforts for M-Enoxaparin and other complex drug candidates may be materially harmed.

Aventis has listed two patents for Lovenox in the Orange Book, the FDA's listing of approved drug products. The FDA Orange Book lists drug products approved under the Federal Food, Drug and Cosmetic Act with therapeutic equivalence evaluations and is used by healthcare professionals to determine, among other things, their guidelines for substitution of generic versions of branded drug products.

The Aventis patents listed in the Orange Book expire on December 24, 2004, which is prior to the date we anticipate we will commercialize M-Enoxaparin, and February 14, 2012, respectively. As is common with generic applications corresponding to branded drugs for which unexpired patents are listed in the Orange Book, we anticipate that Aventis will initiate patent infringement proceedings against Sandoz and us to prevent the marketing of M-Enoxaparin. These proceedings could be costly and time consuming, and ultimately delay or prevent the commercialization of M-Enoxaparin.

M-Dalteparin. We intend to develop a technology-enabled generic version of Fragmin, a LMWH marketed by Pfizer in the United States that is approved for the prevention of DVT and treatment of ACS. In 2002, Fragmin had worldwide sales of approximately $270 million. Our plan is to file a regulatory application for M-Dalteparin in the next 18 to 24 months. Pfizer has listed one patent for Fragmin in the Orange Book which expires January 4, 2005, prior to our plans for commercialization.

Improved Development Products

M118. M118 is a LMWH that we specifically designed to provide improved efficacy and flexible administration as baseline therapy for treating patients with ACS. M118 is currently in preclinical development. We intend to file an investigational new drug application, or IND, prior to the end of the first half of 2005 and begin Phase I clinical trials shortly thereafter.

Sugar-mediated non-invasive delivery. We have identified a novel biological mechanism by which sugars facilitate the transport of molecules, including proteins, across mucosal membranes like those found in the lung. We believe our approach to pulmonary delivery of therapeutic proteins could result in significant advantages over current technologies, including an improved safety profile, higher levels of drug in the blood, or bioavailability, and delivery of larger therapeutic proteins. We are focusing our initial development on pulmonary formulations of several existing drugs, including interferon-beta, also known as Avonex® and Rebif®, erythropoietin, also known as Epogen® and Procrit®, insulin and human growth hormone, or HGH.

Capabilities that enable engineering of complex sugars on therapeutic proteins. Our analytical and sequencing technologies can also be applied to characterize and reengineer sugars that exist on therapeutic proteins. Altering the complex sugar coat of a protein can potentially improve efficacy and tissue targeting, reduce negative side effects and modify the dosing frequency of a protein drug.

Discovery Product Candidates

Recent research has shown that sugars play a critical role in influencing signaling between proteins in pathways to fundamentally affect basic biology. We believe our technology can be utilized to understand the relationship between sugars and disease progression to advance the discovery of novel sugar-based small molecule and antibody drugs to treat a range of diseases, including cancer, cardiovascular disease and inflammatory disease. For example, we have identified specific sugar sequences that have demonstrated potent anti-cancer effects in animals, though early findings in animals do not always predict a response in humans.

Our Business Strategy

Our objective is to become a leading biotechnology company by applying our understanding of complex sugars and our proprietary technologies to drug discovery, development and commercialization. The key elements of our strategy are to (i) maximize the commercial potential of M-Enoxaparin and leverage our analytic capabilities to commercialize other near-term opportunities, (ii) advance our improved development product opportunities into clinical trials, (iii) leverage our proprietary technology and apply our understanding of sugars to create novel therapeutics to address critical unmet needs, (iv) enhance our internal development programs through selective partnering, and (v) establish development capabilities and sales and marketing capabilities focused on key in-hospital markets.

Management Team

We are led by a team of experienced biotechnology and pharmaceutical industry executives and recognized experts in glycobiology, or the study of complex sugars. We believe this team provides us with significant capabilities in the discovery, development and commercialization of therapeutics, resulting from our understanding of complex sugars. If we are unable to retain our management team or recruit additional executives, our business may suffer.

Early-Stage Company

We have a limited operating history and have not yet commercialized any products. We have not been profitable in any quarter since inception. As of March 31, 2004, we had an accumulated deficit of approximately $39.4 million. We recognized net losses of $2.6 million for the first quarter of 2004, $7.9 million for the year ended December 31, 2003 and $4.9 million for the year ended December 31, 2002. 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. We do not know when or whether we will become profitable. The majority of our products are in the early stages of development where failure is common and the technology we are using to discover and develop some of our drugs is novel and unproven. To be successful, we will need to conduct preclinical studies and clinical trials and obtain regulatory approval. Our drug candidates may encounter problems that could result in the lack of regulatory approval to market our products. In addition, several of our product candidates are generic versions of branded drugs for which unexpired patents may be listed in the Orange Book. We will be required to demonstrate therapeutic equivalence to a reference listed drug, and certify that any unexpired listed patent is invalid, unenforceable and/or not infringed prior to commercialization, and our ability to commercialize our product candidates will depend, in part, on our success in intellectual property litigation, if any.

Corporate Information

We were incorporated in Delaware in May 2001 as Mimeon, Inc. In September 2002, we changed our name to Momenta Pharmaceuticals, Inc. Our principal executive offices are located at 43 Moulton Street, Cambridge, Massachusetts 02138. Our telephone number is (617) 491-9700. Our website address is *www.momentapharma.com* . The information on our website is not incorporated by reference into this prospectus and should not be considered to be a part of this prospectus. We have included our website address as an inactive technical reference only.

Unless otherwise stated, all references to "us," "our," "Momenta," "we," the "Company" and similar designations refer to Momenta Pharmaceuticals, Inc. Our logo, trademarks and service marks are the property of Momenta. Other trademarks or service marks appearing in this prospectus are the property of their respective holders.

THE OFFERING

Common stock offered	5,350,000 shares
Common stock to be outstanding after this offering	24,563,183 shares
Use of proceeds	We intend to use the net proceeds to fund the approval and subsequent commercialization of near-term product candidates, development of improved product candidates, research and discovery of novel therapeutics and technologies and working capital, capital expenditures and other general corporate purposes. See "Use of Proceeds."
Proposed NASDAQ National Market symbol	MNTA
Risk factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

The number of shares of our common stock to be outstanding after this offering is based on the number of shares outstanding as of April 30, 2004.

The number of shares of our common stock to be outstanding after this offering does not take into account:

- 1,148,897 shares of common stock issuable upon the exercise of outstanding stock options as of April 30, 2004 at a weighted average exercise price of $0.64 per share;
- an aggregate of 4,473,437 shares of common stock reserved for future issuance under our 2004 stock incentive plan and our 2004 employee stock purchase plan as of the completion of this offering; and
- 16,000 shares of common stock issuable upon the exercise of an outstanding warrant that will remain outstanding after this offering at an exercise price of $2.2422 per common share.

Unless otherwise noted, the information in this prospectus assumes that the underwriters do not exercise their over-allotment option, reflects a 1.28-for-1 stock split of our common stock, which was effected on May 10, 2004, reflects the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 15,014,390 shares of common stock upon the completion of this offering and gives effect to the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated by-laws upon the closing of this offering.

SUMMARY FINANCIAL AND OPERATING DATA

The following table presents a summary of our historical financial information. You should read this information in conjunction with our financial statements and related notes and the information under "Selected Financial and Operating Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," all included elsewhere in this prospectus.

The pro forma net loss attributable to common stockholders per share information is computed using the weighted average number of common shares outstanding, after giving pro forma effect to the automatic conversion of all shares of our redeemable convertible preferred stock outstanding at March 31, 2004 into an aggregate of 15,014,390 shares of our common stock effective upon the completion of this offering, as if the conversion had occurred at the date of the original issuance. This pro forma information does not give effect to the issuance of common stock upon the exercise of the outstanding stock options or the outstanding warrant.

	Period from Date of Inception (May 17, 2001) through December 31, 2001	Year Ended December 31,		Three Months Ended March 31,	
		2002	2003	2003	2004
				Unaudited	
	(In thousands, except per share information)				
Statements of Operations Data:					
Collaboration revenue	$ —	$ —	$ 1,454	$ —	$ 1,037
Operating expenses:					
Research and development	206	2,174	5,348	790	2,240
General and administrative	167	2,712	4,082	706	1,409
Total operating expenses	373	4,886	9,430	1,496	3,649
Loss from operations	(373)	(4,886)	(7,976)	(1,496)	(2,612)
Interest income	2	17	74	3	41
Interest expense	—	—	(43)	(5)	(11)
Net loss	(371)	(4,869)	(7,945)	(1,498)	(2,582)
Deemed dividend	—	—	—	—	(20,389)
Dividends and accretion to redeemable convertible preferred stock	(22)	(520)	(1,899)	(164)	(817)
Net loss attributable to common stockholders	$ (393)	$ (5,389)	$ (9,844)	$ (1,662)	$ (23,788)
Basic and diluted net loss attributable to common stockholders per common share	$ (6.74)	$ (5.70)	$ (5.02)	$ (1.13)	$ (9.04)
Weighted average shares outstanding—basic and diluted	58	946	1,961	1,474	2,631
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share			$ (0.92)		$ (1.53)
Unaudited pro forma weighted average shares outstanding—basic and diluted			10,718		15,550

The pro forma as adjusted balance sheet data gives effect to our sale of 5,350,000 shares of common stock in this offering at an assumed initial public offering price of $14.00 per share, after deducting estimated underwriting discounts and commissions and offering expenses payable by us, and the automatic conversion of all outstanding shares of our convertible preferred stock at March 31, 2004 into an aggregate of 15,014,390 shares of common stock upon the completion of this offering.

	As of March 31, 2004	
	Actual	Pro Forma As Adjusted
	Unaudited (In thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 16,585	$ 84,835

Short-term investments	14,615	14,615
Working capital	31,223	99,473
Total assets	34,516	102,766
Line of credit obligation–net of current portion	289	289
Redeemable convertible preferred stock	48,432	—
Accumulated deficit	(39,417)	(39,417)
Total stockholders' equity (deficit)	(16,728)	99,954

RISK FACTORS

This offering involves a high degree of risk. You should consider carefully the risks and uncertainties described below and the other information in this prospectus, including the financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in shares of our common stock. If any of the following risks or uncertainties actually occurs, our business, prospects, financial condition and operating results would likely suffer, possibly materially. In that event, the market price of our common stock could decline and you could lose all or part of your investment.

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 March 31, 2004, our accumulated deficit was approximately $39.4 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. To date, we have invested approximately $5.0 million on the development of M-Enoxaparin. Our near-term ability to generate revenues and our future success, in part, depends on the development and commercialization of M-Enoxaparin.

We plan to prepare and submit an application 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 a new drug application, or 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 Aventis, the innovator of Lovenox.

We will likely face costly and time consuming intellectual property litigation with 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. In August 2003, Aventis sued Amphastar Pharmaceuticals, Inc., or Amphastar, and Teva Pharmaceuticals USA, Inc., or Teva, alleging, among other things, that the generic versions of Lovenox intended to be marketed by those companies infringe Aventis' Patent No. 5,389,618, which is scheduled to expire on February 14, 2012. We expect to face patent litigation if and when we submit 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 the following circumstance:

- Sandoz has received ANDA approval for M-Enoxaparin; and
- a federal district court has determined that marketing M-Enoxaparin will not infringe Aventis' patent rights or that the relevant Aventis patent rights are invalid or unenforceable, or Sandoz, in its reasonable judgment, concludes that a federal district court's determination in a patent infringement suit between Aventis and a third party would permit the marketing of M-Enoxaparin; but
- Sandoz has neither settled litigation with Aventis nor received an unappealable judgment that marketing M-Enoxaparin will not infringe Aventis' patent rights, nor has any third party received an unappealable judgment that the relevant Aventis patent rights are invalid or unenforceable or from which Sandoz could conclude that the marketing of M-Enoxaparin would not infringe Aventis' patent rights.

Should Sandoz elect to proceed in this manner, we could face substantial patent liability damages, including possible treble damages, if a final court decision is adverse to us. Sandoz has agreed to indemnify us for these liabilities, subject to Sandoz's ability to offset certain of these liabilities against the profit-sharing amounts, the royalties and the commercial milestone payments otherwise due to us from the marketing of M-Enoxaparin. Further, if we are unsuccessful in any litigation, the court could issue a permanent injunction preventing us from marketing M-Enoxaparin for the life of Aventis' patent. In addition, Aventis has significantly greater resources than we do, and litigation with Aventis could last a number of years, potentially delaying or prohibiting the commercialization 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 Aventis. 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.

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

In mid 2003, Amphastar and Teva 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, we may never achieve significant market share for M-Enoxaparin, 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 certification that any patents listed with the FDA for the drug are invalid or not infringed by the manufacture, use or sale of the generic drug, or "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 and we could launch M-Enoxaparin.

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 further developing our M-Enoxaparin laboratory-scale processes, manufacturing the drug substance for M-Enoxaparin and providing certain other development services relating to M-Enoxaparin. We expect to depend on additional third parties to manufacture the drug product and provide analytical services with respect to M-Enoxaparin. We have not yet completed the manufacturing of a sufficient number of registration lots of M-Enoxaparin necessary to file our regulatory submission and we may run into unforeseen 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, such as alternatives to LMWHs or improved non-invasive delivery methods. 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.

The pharmaceutical market is highly competitive and rapidly changing. 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, 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 and M118;
- the cost of litigation, including potential patent litigation with Aventis relating to Lovenox, or with others, as well as any damages, including possibly treble damages, that may be owed to 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 short-term investments, 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 expected net proceeds from this offering, will be sufficient to fund our operations for at least 36 months. 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 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 currently do not have any product liability insurance, but plan to obtain such insurance at appropriate levels prior to initiating studies in humans or clinical trials and at higher levels prior to marketing any of our drug candidates. 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.

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, 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 current good manufacturing practice, or cGMP. We cannot predict whether any of our generic product candidates will meet FDA requirements for approval.

On February 19, 2003, a Citizen Petition was submitted to the FDA on behalf of Aventis requesting that the Commissioner of Food and Drugs withhold approval of any ANDA for a generic version of Lovenox until the conditions set forth in Aventis' petition are satisfied. In its petition, Aventis principally requested that, until enoxaparin has been fully characterized, the FDA refrain from approving any ANDA citing Lovenox as the reference listed drug, until the manufacturing process used to create the generic product is determined to be equivalent to Aventis' manufacturing process for Lovenox or the generic application is supported by proof of equivalent safety and effectiveness demonstrated through clinical trials. On February 12, 2004, Aventis submitted a supplement to its Citizen Petition, citing several new discoveries that supported its previous requests. To date, the FDA has not yet publicly responded to Aventis' requests nor has it issued any public interpretation of the guidelines for therapeutic equivalence as they may apply to LMWH products such as Lovenox or Fragmin. 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 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 institutional review boards, or 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 third-party and government 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 also exists substantial uncertainty concerning third-party reimbursement for the use of any drug product incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the product is approved by the FDA. 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 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 may have sufficient market power to demand significant price reductions. As a result of actions by these 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 eventually 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 that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our products and could seriously harm our business. 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.

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 complex 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 fiscal years ended 2001, 2002 and 2003, we spent approximately $0, $10,000 and $17,500 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 we fail to meet certain development milestones, 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 will provide 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 noncompliances 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, the bulk of which are 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. In all of the above cases, we do not indemnify the parties for claims resulting from the negligence or willful misconduct of the indemnified party.

We maintain insurance coverage which we believe will 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 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.

Risks Relating to This Offering

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We cannot specify with certainty the particular uses of the net proceeds that we will receive from this offering. Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the "Use of Proceeds" section of this prospectus. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. The failure by our management to apply these funds effectively could have a material adverse effect on our business. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The assumed initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $9.93 per share, based on an assumed initial public offering price of $14.00 per share. Further, investors purchasing common stock in this offering will contribute approximately 62% of the total amount invested by stockholders since our inception, but will own only approximately 22% of the shares of common stock outstanding.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less than the price offered to the public in this offering when they purchased their shares and the exercise of stock options granted to our employees. As of April 30, 2004, options to purchase 1,148,897 shares of common stock at a weighted average exercise price of $0.64 per share were outstanding, and a warrant to purchase 12,500 shares of our Series A double prime convertible preferred stock, with an exercise price of $2.87, was outstanding. After this offering, this warrant will be exercisable for 16,000 shares of common stock at an exercise price of $2.2422 per common share. The exercise of any of these options or the warrant would result in additional dilution. As a result of this dilution, investors purchasing stock in this offering may receive significantly less than the purchase price paid in this offering in the event of a liquidation.

Our stock price is likely to be volatile, and the market price of our common stock after this offering may drop below the price you pay.

Prior to this offering, there has been no public market for our common stock, and an active public market for our common stock may not develop or continue after this offering. If you purchase shares of our common stock in this offering, you will not pay a price established in a public marketplace. Rather, you will pay the price that we negotiate with the underwriters, which may not be indicative of market prices.

Market prices for securities of biotechnology companies have been particularly volatile. 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 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.

An active trading market for our common stock may not develop.

Prior to this offering, there has been no public market for our common stock. Although we have applied to have our common stock approved for quotation on the NASDAQ National Market, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price for our common stock will be determined through negotiations with the underwriters. This initial public offering price may vary from the market price of our common stock after the offering. Investors may not be able to sell their common stock at or above the initial public offering price.

Insiders will continue to have substantial control over Momenta after this offering and could delay or prevent a change in corporate control.

After this offering, our directors, executive officers and principal stockholders, together with their affiliates, will beneficially own, in the aggregate, approximately 70.6% of our outstanding common stock, or 68.4% if the underwriters exercise their over-allotment option. 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 that will become effective upon the completion of this offering 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.

If there are substantial sales of our common stock, our stock price could decline.

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock could decline significantly. All of the shares being sold in this offering will be freely tradable without restriction or further registration under the federal securities laws, unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act.

After this offering, we will have outstanding 24,563,183 shares of common stock based on the number of shares outstanding as of April 30, 2004. This includes the 5,350,000 shares that we are selling in this offering, which may be resold in the public market immediately. The remaining

19,213,183 shares, or 78.2% of our outstanding shares after this offering, are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold in the near future as set forth below.

Number of Shares and % of Total Outstanding	Date Available for Sale Into Public Market
31,120 shares, or 0.16%	Beginning 90 days after the completion of this offering, depending on the requirements of the federal securities laws.
15,792,606 shares, or 82.2%	180 days after the date of this prospectus due to lock-up agreements between the holders of these shares and the underwriters. However, the underwriters can waive the provisions of these lock-up agreements and allow these stockholders to sell their shares at any time.
3,389,457 shares, or 17.64%	Between 180 and 365 days after the date of this prospectus, depending on the applicable requirements of the federal securities laws.

Upon completion of this offering, subject to certain conditions, holders of an aggregate of approximately 18,601,275 shares of common stock will have rights with respect to the registration of these shares of common stock with the Securities and Exchange Commission. If we register their shares of common stock following the expiration of the lock-up agreements, they can sell those shares in the public market.

Promptly following this offering, we intend to register approximately 5,717,380 shares of common stock that are authorized for issuance under our stock plans, employee stock purchase plan and outstanding stock options. As of April 30, 2004, 1,148,897 shares were subject to outstanding options. Once we register the shares authorized for issuance under our stock plans, they can be freely sold in the public market upon issuance, subject to the lock-up agreements referred to above and the restrictions imposed on our affiliates under Rule 144.

SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements.

NOTICES TO INVESTORS

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. We are offering to sell shares of common stock and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of the common stock.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of 5,350,000 shares of common stock in this offering will be approximately $68.3 million, assuming an initial public offering price of $14.00 per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option, we estimate that we will receive additional net proceeds of approximately $10.5 million. We intend to use the majority of the net proceeds 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; and
- the development of improved product candidates, including using approximately $15.0 million to $20.0 million to develop M118 through Phase I and Phase II clinical trials and $15.0 million to $20.0 million for the initial development of pulmonary formulations of therapeutic proteins.

We anticipate using the remaining net proceeds of this offering to fund:

- the research and discovery of novel therapeutics and technologies; and
- working capital, capital expenditures and other general corporate purposes.

In addition, we may also use a portion of the proceeds for the acquisition of, or investment in, companies, technologies, products or assets that complement our business. However, we have no present understandings, commitments or agreements to enter into any potential acquisitions or investments.

The amounts and timing of our actual expenditures will depend upon numerous factors, including the timing and success of any clinical trials we may commence in the future, the timing of regulatory submissions, the status of our research and development efforts and timing, the amount of proceeds actually raised in this offering, the amount of cash generated by our operations, the amount of competition we face and the success we have with obtaining any required licenses and entering into collaboration arrangements. As a result, our management will have broad discretion to allocate the net proceeds from this offering. Pending utilization of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term investment grade and U.S. government securities.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our common stock. We currently intend to retain earnings, if any, to finance the growth and development of our business and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in current or future financing instruments and other factors our board of directors deems relevant.

CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2004:

- on an actual basis;
- on a pro forma as adjusted basis to reflect (a) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 15,014,390 shares of common stock upon the closing of this offering, and (b) the issuance and sale of 5,350,000 shares of common stock upon completion of this offering at an assumed initial public offering price of $14.00 per share, after deducting estimated underwriting discounts and commissions and offering expenses payable by us.

You should read this table together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus.

	As of March 31, 2004	
	Actual	Pro Forma As Adjusted
	(In thousands)	
Cash and cash equivalents and short-term investments	$ 31,200	$ 99,450
Line of credit obligation—net of current portion	289	$ 289
Redeemable convertible preferred stock, $0.01 par value per share; 12,000,000 shares authorized actual and no shares authorized pro forma as adjusted; 11,730,012 shares outstanding actual and no shares outstanding pro forma as adjusted	48,432	—
Stockholders' equity (deficit):		
Preferred stock, par value $0.01 per share; no shares authorized actual and 5,000,000 shares authorized pro forma as adjusted; no shares outstanding actual and pro forma as adjusted	—	—
Common stock, par value $0.0001 per share; 30,000,000 and 100,000,000 shares authorized actual and pro forma as adjusted, respectively; 4,193,355 shares outstanding actual and 24,557,745 shares outstanding pro forma as adjusted	—	2
Additional paid-in capital	25,963	142,643
Accumulated other comprehensive loss	(7)	(7)
Due from officer	(35)	(35)
Deferred compensation	(3,231)	(3,231)
Accumulated deficit	(39,417)	(39,417)
Total stockholders' equity (deficit)	(16,728)	99,955
Total capitalization	$ 31,993	$ 100,244

The above data excludes:

- 1,065,437 shares of common stock issuable upon exercise of options outstanding as of March 31, 2004 with a weighted average exercise price of $0.64 per share;
- an aggregate of 4,473,437 shares of common stock reserved for future issuance under our 2004 stock incentive plan and our 2004 employee stock purchase plan; and
- 16,000 shares of common stock issuable upon the exercise of a warrant to purchase shares of Series A double prime convertible preferred stock that will remain outstanding after this offering at an exercise price of $2.2422 per common share.

DILUTION

Our historical net tangible book value as of March 31, 2004 was a deficit of $16.7 million, or $3.99 per share, based on 4,193,355 shares of common stock outstanding as of March 31, 2004. Historical net tangible book value per share is determined by dividing our total tangible assets less total liabilities and redeemable convertible preferred stock by the actual number of outstanding shares of our common stock. Our pro forma net tangible book value as of March 31, 2004 was $31.7 million, or $1.65 per share, based on 19,207,745 shares of common stock outstanding after giving effect to the automatic conversion of all outstanding shares of our redeemable convertible preferred stock into common stock upon the closing of this offering. Pro forma net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the pro forma number of shares of common stock outstanding before giving effect to this offering.

After giving effect to our sale of 5,350,000 shares of common stock in this offering, at an assumed initial public offering price of $14.00 per share, less estimated underwriting discounts and commissions and offering expenses payable by us, our pro forma net tangible book value as of March 31, 2004 would have been $4.07 per share. This represents an immediate increase in pro forma net tangible book value per share of $8.06 to existing stockholders and immediate dilution in pro forma net tangible book value of $9.93 per share to new investors purchasing our common stock in the offering at the assumed initial public offering price. Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the initial public offering price per share paid by a new investor. The following table illustrates the per share dilution without giving effect to the over-allotment option granted to the underwriters:

Assumed initial public offering price per share		$ 14.00
Historical net tangible book value per share at March 31, 2004	(3.99)	
Increase per share attributable to the conversion of redeemable convertible preferred stock	5.64	
Pro forma net tangible book value per share at March 31, 2004	1.65	
Increase per share attributable to new investors	2.42	
Pro forma net tangible book value per share after the offering		4.07
Dilution of net tangible book value per share to new investors		$ 9.93

If the underwriters exercise their over-allotment option in full, the pro forma net tangible book value per share after the offering would be $4.35 per share, the increase in net tangible book value per share to existing stockholders would be $8.34 per share and the dilution to new investors would be $9.65 per share.

The following table summarizes, on a pro forma basis, as of March 31, 2004, the differences between the number of shares of common stock purchased from us, the total cash consideration paid and the average price per share paid by our existing stockholders and by new investors in this offering. We have used the initial public offering price of $14.00 per share, and have not deducted the underwriting discount and commissions and other expenses of the offering in our calculations:

	Shares Purchased		Total Consideration		
	Number	Percent	Amount	Percent	Average Price Per Share
Existing stockholders	19,207,745	78.2%	$ 45,983,406	38.0%	$ 2.39
New investors	5,350,000	21.8	74,900,000	62.0	14.00
Total	24,557,745	100.0%	120,883,406	100.0%	

The share data in the table above is based on shares outstanding as of March 31, 2004 and excludes:

- 1,065,437 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2004 at a weighted average exercise price of $0.64 per share;
- an aggregate of 4,473,437 shares of common stock reserved for future issuance under our 2004 stock incentive plan and our 2004 employee stock purchase plan as of the completion of this offering; and
- 16,000 shares of common stock issuable upon the exercise of an outstanding warrant to purchase shares of Series A double prime convertible preferred stock that will remain outstanding after this offering at an exercise price of $2.2422 per common share.

If the underwriters' over-allotment option is exercised in full, the following will occur:

- the percentage of shares of common stock held by existing stockholders will decrease to approximately 75.7% of the total number of shares of our common stock outstanding after this offering; and
- the number of shares held by new investors will be increased to 6,152,500 or approximately 24.3% of the total number of shares of our common stock outstanding after this offering.

SELECTED FINANCIAL AND OPERATING DATA

You should read the following selected financial information together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the statement of operations data for the three months ended March 31, 2003 and 2004 and the balance sheet data at March 31, 2004 from our unaudited financial statements which are included in this prospectus. The unaudited financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments necessary for a fair presentation of the information set forth therein. We have derived the statement of operations data for the period from inception (May 17, 2001) through December 31, 2001, or Fiscal 2001, and for the years ended December 31, 2002 and 2003, or Fiscal 2002 and 2003, respectively, and the balance sheet information at December 31, 2002 and 2003 from our audited financial statements which are included in this prospectus. We have derived the balance sheet data at December 31, 2001 from our audited financial statements, which are not included in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period. The pro forma net loss attributable to common stockholders per share information is computed using the weighted average number of common shares outstanding, after giving pro forma effect to the automatic conversion of all shares of our redeemable convertible preferred stock outstanding at March 31, 2004 into shares of our common stock effective upon the completion of this offering, as if the conversion had occurred at the date of the original issuance. This pro forma data does not give effect to the issuance of common stock upon the exercise of outstanding stock options or the outstanding warrant.

	Period from Inception (May 17, 2001) through December 31, 2001	Year Ended December 31,		Three Months Ended March 31,	
		2002	2003	2003	2004
	(In thousands, except per share information)				
Statements of Operations Data:					
Collaboration revenue	$ —	$ —	$ 1,454	$ —	$ 1,037
Operating expenses:					
Research and development	206	2,174	5,348	790	2,240
General and administrative	167	2,712	4,082	706	1,409
Total operating expenses	373	4,886	9,430	1,496	3,649
Loss from operations	(373)	(4,886)	(7,976)	(1,496)	(2,612)
Interest income	2	17	74	3	41
Interest expense	—	—	(43)	(5)	(11)
Net loss	(371)	(4,869)	(7,945)	(1,498)	(2,582)
Deemed dividend	—	—	—	—	(20,389)
Dividends and accretion to redeemable convertible preferred stock	(22)	(520)	(1,899)	(164)	(817)
Net loss attributable to common stockholders	$ (393)	$ (5,389)	$ (9,844)	$ (1,662)	$ (23,788)
Basic and diluted net loss attributable to common stockholders per common share	$ (6.74)	$ (5.70)	$ (5.02)	$ (1.13)	$ (9.04)
Weighted average shares outstanding—basic and diluted	58	946	1,961	1,474	2,631
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share			$ (0.92)		$ (1.53)
Unaudited pro forma weighted average shares outstanding—basic and diluted			10,718		15,550

	As of December 31,			As of March 31,
	2001	2002	2003	2004
	(In thousands)			
Balance Sheet Data:				
Cash and cash equivalents	$ 181	$ 1,471	$ 4,613	$ 16,585
Short-term investments	—	—	7,994	14,615
Working capital	(128)	633	13,044	31,223
Total assets	184	2,500	16,084	34,516
Line of credit obligation—net of current portion	—	—	372	289
Redeemable convertible preferred stock	22	6,427	27,225	48,432
Accumulated deficit	(396)	(5,785)	(15,629)	(39,417)
Total stockholders' deficit	(148)	(4,831)	(13,779)	(16,728)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read together with "Selected Financial and Operating Data," and our financial statements and accompanying notes appearing elsewhere in this prospectus. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" and elsewhere in this prospectus.

Overview

Momenta is a biotechnology company specializing in the sequencing and engineering 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 near-term technology-enabled generic products. Our most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox, the most widely prescribed LMWH in the world. We have formed a collaboration with Sandoz to jointly develop, manufacture and commercialize M-Enoxaparin.

Our revenues for the three months ended March 31, 2004 and the year ended December 31, 2003 were $1.0 million and $1.5 million, respectively, consisting of amortization of the initial payment due under our collaboration with Sandoz and amounts payable to us by Sandoz for reimbursement of research and development services and reimbursement of development costs for M-Enoxaparin. As a result of our collaboration with Sandoz, we ceased to be considered a development-stage company for financial statement reporting purposes in 2003. We have had no other revenue since inception other than interest on short-term investments.

We commenced operations in May 2001. Since our inception, we have incurred annual net losses. As of March 31, 2004, we had an accumulated deficit of $39.4 million. We recognized net losses of $2.6 million for the first quarter of 2004, $7.9 million for Fiscal 2003 and $4.9 million for Fiscal 2002. 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 and have funded our operations primarily through the private placement of equity securities. In February 2004, we raised net cash proceeds of $20.4 million from the sale of Series C redeemable convertible preferred stock. Through March 31, 2004, we have raised net cash proceeds of $45.4 million through the private placement of 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, such as alternatives to LMWHs or improved non-invasive delivery methods. 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; scaling-up and manufacturing M-Enoxaparin for FDA approval and commercialization; and marketing M-Enoxaparin and achieving 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, $2.5 million of revenue from our inception through March 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, 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.

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, 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: applying a sugar-mediated technology to improve the non-invasive delivery of therapeutic proteins and applying capabilities which enable engineering of complex sugars on therapeutic proteins to improve the efficacy, reduce side effects and modify the dosage of protein drugs. In our drug discovery program, 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, business development and human resource functions. Other costs include facility costs not otherwise included in research and development expense and professional fees for legal and accounting services.

After this offering, we anticipate increases in general and administrative expense for investor relations and other activities associated with operating as a publicly-traded company. These increases will also 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.

Sandoz Collaboration

In November 2003, we entered into an exclusive collaboration and license agreement with Sandoz to jointly develop and commercialize M-Enoxaparin in the United States. For 2003, we were owed an initial payment of $0.6 million for reimbursement of specified development costs incurred prior to entering into the agreement, and $1.4 million for research and development services and other reimburseable costs incurred since the agreement commenced. The amount receivable of $2.0 million was billed and collected in full in 2004. The revenue from the initial payment is being recognized over the remaining life of the research and development program, which is estimated to be four years. We may receive additional research and development funding through product approval and launch, milestone payments and profit sharing payments or royalties on any product sales.

Results of Operations

Three Months Ended March 31, 2004 and 2003

Revenue

Revenue for the first quarter of 2004 was $1.0 million, which was attributable to our collaboration agreement with Sandoz signed in November 2003. This revenue includes $36,789 in amortization of an initial payment made to us by Sandoz and $1.0 million payable to us for research and development services and other reimbursable costs. We had zero revenues in the first quarter of 2003.

Research and Development

The following table summarizes the primary components of our research and development expense for our principal research and development programs for the three months ended March 31, 2003 and 2004.

Research and Development Program	2003	2004
M-Enoxaparin	$ 526,426	$ 708,151
M118	44,592	787,224
Drug delivery	91,011	346,742
Other discovery and development programs	128,114	397,653
Total research and development expense	$ 790,143	$ 2,239,770

Research and development expense for the first quarter of 2004 was $2.2 million compared to $0.8 million in the first quarter of 2003. Our increase in research and development expenses principally resulted from an increase of $0.7 million in the M118 program in the first quarter of 2004 due to an increase of $0.5 million in contracted manufacturing costs as we commenced the manufacturing of pre-clinical product, an increase of $0.3 million in our drug delivery program due to increased staffing

and related expenses, and an increase of $0.2 million of expenses associated with the M-Enoxaparin program, primarily reflecting an increase in staffing and related expenses as a result of our collaboration with Sandoz. In addition, costs increased in our drug delivery and other discovery and development programs primarily due to increases in staffing and related expenses due to increased headcount.

General and Administrative

General and administrative expense for the first quarter of 2004 was $1.4 million compared to $0.7 million in the first quarter of 2003. General and administrative expense increased due to an increase of $0.2 million in stock compensation expense, an increase of $0.2 million in consulting and professional fees, an increase of $0.1 million in personnel and related costs due to increased headcount, and an increase of $0.1 million in legal costs due to an increase in corporate and patent-related legal services.

Interest Income and Expense

Interest income increased to $41,635 in the first quarter of 2004 from $3,808 in the first quarter of 2003, primarily due to higher average investment balances in 2004 as a result of the proceeds from our issuance of Series B preferred stock in May 2003 and Series C preferred stock in February 2004. Interest expense increased from the first quarter of 2003 to the first quarter of 2004 due to a higher average balance on our bank line of credit in 2004.

Years Ended December 31, 2003, 2002 and the Period from Inception (May 17, 2001) to December 31, 2001

Revenue

Revenue for Fiscal 2003 was $1.5 million, which was attributable to our collaboration agreement with Sandoz signed in November 2003. This revenue includes $24,526 in amortization of an initial payment made to us by Sandoz and $1.4 million payable to us for research and development services and other reimbursable costs. We had zero revenues in Fiscal 2002 and 2001.

Research and Development

Research and development expense for Fiscal 2003 was $5.3 million compared to $2.2 million in Fiscal 2002 and $0.2 million in Fiscal 2001. In Fiscal 2003 compared with Fiscal 2002, our increased research and development expense 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 Fiscal 2002 compared to Fiscal 2001, research and development expenses increased primarily due to the growth of our operations in 2002. In addition, Fiscal 2002 include charges totaling $0.6 million for license fees.

The following table summarizes the primary components of our research and development expense for our principal research and development programs for Fiscal 2001, 2002 and 2003.

Research and Development Program	2001	2002	2003
M-Enoxaparin	$ —	$ 960,719	$ 3,927,826
M118	—	—	541,654
Other discovery and development programs	206,437	1,212,920	878,365
Total research and development expense	$ 206,437	$ 2,173,639	$ 5,347,845

General and Administrative

General and administrative expense for Fiscal 2003 was $4.1 million compared to $2.7 million in Fiscal 2002 and $0.2 million Fiscal 2001. In Fiscal 2003 compared to Fiscal 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. General and administrative expenses increased in Fiscal 2002 compared to Fiscal 2001 primarily due to our limited scope of operations in 2001.

Interest Income

Interest income increased to $73,969 in Fiscal 2003 from $16,965 in Fiscal 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 income increased from Fiscal 2001 to Fiscal 2002 due to our Series A Prime and Series A Double Prime financings.

Interest Expense

Interest expense of $42,920 in Fiscal 2003 related to amounts drawn from our bank line of credit. There were zero borrowings and zero interest expense in Fiscal 2001 and 2002.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the private placement of equity securities. As of March 31, 2004, we have received net proceeds of $45.4 million from the issuance of redeemable convertible preferred stock. At March 31, 2004, we had $31.2 million in cash, cash equivalents and short-term investments. In February 2004, we sold 2,612,696 shares of our Series C redeemable convertible preferred stock for net proceeds of $20.4 million to existing preferred stockholders and one new investor. These shares contain a beneficial conversion feature based on the fair value of our 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.

Net cash used in operating activities was $1.7 million for the first quarter of 2004, $1.4 million for the first quarter 2003, $8.0 million for Fiscal 2003, $3.7 million for Fiscal 2002, and $45,547 for Fiscal 2001. 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 $6.7 million for the first quarter of 2004, $0.1 million for the first quarter of 2003, $8.5 million for Fiscal 2003 and $0.9 million for Fiscal 2002. In the first quarter of 2004, we used $7.4 million of cash to purchase short-term investments and had $0.8 million in maturities of short-term investments. In the first quarter of 2003, we used $0.1 million to purchase equipment. We used $8.0 million of cash in 2003 to purchase short-term investments and used $0.5 million and $0.9 million in 2003 and 2002, respectively, to purchase equipment and leasehold improvements. We expect approximately $2.0 million in capital expenditures for 2004, principally related to the purchase of laboratory equipment and leasehold improvements.

In the first quarter of 2004, our financing activities provided $20.3 million, reflecting the issuance of our Series C redeemable convertible preferred stock for net proceeds of $20.4 million. In the first quarter of 2003, $0.9 million was provided by financing activities, primarily $0.9 million from drawing on a bank line of credit. Net cash provided by financing activities was $19.7 million for Fiscal 2003, $5.9 million for Fiscal 2002 and $0.2 million for Fiscal 2001. Cash provided for 2003 primarily reflects

the issuance of 6,440,678 shares of Series B redeemable convertible preferred stock resulting in net cash proceeds of $18.9 million and proceeds from a line of credit obligation of $1.0 million, offset by lease payments of $0.3 million. Cash provided in Fiscal 2002 and 2001 primarily reflects the proceeds from the issuance of Series A redeemable convertible preferred stock.

The following table summarizes our contractual obligations at December 31, 2003 and the effects such obligations are expected to have on our liquidity and cash flows in future periods.

Payments Due by Period

Contractual Obligations	Total	2004	2005 through 2006	2007 through 2008	After 2008
License maintenance obligations(1)	$ 502,500	$ 67,500	$ 205,000	$ 230,000	
Short and long-term line of credit obligation	713,229	329,996	383,233	—	$ —
Operating lease obligations	348,464	342,021	5,970	473	—
Total contractual cash obligations(2)(3)	$ 1,564,193	$ 739,517	$ 594,203	$ 230,473	$ —

(1) After 2008, the annual obligations, which extend indefinitely, range from $182,000 to $217,500 per year.

(2) We have signed a non-binding letter of intent with a third party to enter into a ten year lease for office and laboratory space which, if entered into upon the same terms as the letter of intent, would add the following amounts to our operating lease obligations: 2004: $321,332; 2005 through 2006: $2,059,767; 2007 through 2008: $2,345,843; after 2008: $7,496,478.

(3) In May 2004, we amended an agreement with a third party to provide up to an additional $1.6 million of process development and production work, for a total remaining cash obligation of up to $2.0 million, which we expect to pay in 2004 and 2005.

We anticipate that our current cash, cash equivalents and short-term investments, 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 expected net proceeds from this offering will be sufficient to fund our operations for at least 36 months. 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 $2.0 million as of March 31, 2004 from our collaboration with Sandoz. We did not receive payments from any collaborations from our inception through December 31, 2003. Under our collaboration with Sandoz, 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 the net proceeds from this offering 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 the net proceeds 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; and

- the development of improved product candidates, including using approximately $15.0 million to $20.0 million to develop M118 through Phase I and Phase II clinical trials and $15.0 million to $20.0 million for the initial development of pulmonary formulations of therapeutic proteins.

We anticipate using the remaining net proceeds of this offering to fund:

- the research and discovery of novel therapeutics and technologies; and
- working capital, capital expenditures and other general corporate purposes.

In addition, we may also use a portion of the proceeds for the acquisition of, or investment in, companies, technologies, products or assets that complement our business. However, we have no present understandings, commitments or agreements to enter into any potential acquisitions or investments.

We expect to incur substantial costs and losses as we continue to expand our research and development activities, particularly as we progress M118 into Phase I clinical trials. Our funding requirements will depend on numerous factors, including:

- the progress of development of M-Enoxaparin, M-Dalteparin 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 M118 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 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 2002 and 2003, certain grants of stock options were made at exercise prices 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 have not been publicly traded, market factors historically considered in valuing stock and stock option grants include comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we are issuing, pricing of private sales of our redeemable convertible preferred stock, prior valuations of stock grants and the effect of events that have occurred between the time of such grants, economic trends, and the comparative rights and preferences of the security being granted compared to the rights and preferences of our other outstanding equity.

The fair value of our common stock is determined by our board of directors. In the absence of a public trading market for our common stock, our board of directors considers 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

In January 2003, the FASB issued Financial Interpretation Number 46, *Consolidation of Variable Interest Entities* (FIN 46). This interpretation requires existing unconsolidated variable interest entities to be consolidated by their primary beneficiaries if the entities do not effectively disperse risks among parties involved. It explains how to identify variable interest entities and how an enterprise assesses its interest in a variable interest entity to decide whether to consolidate that entity. This interpretation, as amended, applies in the first fiscal year or interim period beginning after December 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. Since we do not currently have any unconsolidated variable interest entities, we do not expect the adoption of FIN 46 to have a material impact on our financial position or results of operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity.* This statement establishes how a company classifies and measures certain financial instruments with characteristics of both liabilities and equity, including

redeemable preferred stock. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise effective at the beginning of the interim period commencing July 1, 2003, except for mandatory redeemable financial instruments of nonpublic companies, which is effective for fiscal periods beginning after December 31, 2004. We do not expect the adoption of this statement will have a material impact on its financial statements.

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 eighteen 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. If market interest rates were to increase immediately and uniformly by 10% from levels at March 31, 2004, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. While our cash and investment balances will increase upon completion of the offering contemplated by this prospectus, we will have the ability to hold our fixed income investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

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 products. Through detailed analysis of the molecular structure of complex sugars, our proprietary technology provides a more complete understanding of the roles that sugars play in cellular function, disease and drug action. Based on our understanding of complex sugars, we have developed a diversified pipeline of novel discovery and development candidates and near-term product opportunities. Our business strategy is to utilize near-term product opportunities to provide a funding source for our discovery and development 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.

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox, a LMWH, used to prevent and treat DVT, and treat ACS. Aventis reported worldwide sales of Lovenox to be approximately $1.9 billion in 2003, and analysts project sales to exceed $3.0 billion in 2008. The development of M-Enoxaparin is enabled by our ability to analyze sugars. 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. In addition, we intend to develop a technology-enabled generic version of Fragmin, another LMWH. Currently, there are no FDA approved generic equivalents of Lovenox or Fragmin.

We intend to use our technology to improve existing drugs and develop novel drugs. Our novel development opportunities include:

- M118, which is a LMWH specifically designed for the treatment of ACS;
- a technology designed to use specific sugar sequences to improve the non-invasive delivery of therapeutic proteins, such as interferon-beta, erythropoietin, insulin and HGH; and
- capabilities that are designed to enable engineering of complex sugars on therapeutic proteins to improve the efficacy, reduce side effects and modify the dosing frequency of protein drugs.

Our drug discovery program, which is focused initially in oncology, is designed to leverage our understanding of sugar biology. We believe that we will be able to use this understanding to develop sugar-based drugs and identify specific biological processes and pathways that can be targeted with small molecule or antibody drugs.

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, are critical molecules that regulate biological processes and pathways in the human body. Due to the complex molecular structures of sugars and the lack of sophisticated analytical tools and methods required to examine the minute quantities of sugars that occur in nature, sugars have not been well defined or their molecular structures determined. Without being able to identify specific structures, it is not presently possible to monitor how these sugars act in biological organisms. As a consequence, the development of sugar-based drugs 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 critical biological processes and pathways will provide significant commercial opportunities for drug discovery and development.

Complex sugars influence fundamental biological processes and pathways, disease onset and progression and drug action. 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 a fundamental role in numerous major diseases, such as cancer, cardiovascular disease, inflammatory disease and viral infection.

Biology of Complex Sugars

Complex sugars exist within, on the surface of and between cells, where they are attached to proteins, lipids, and other biologic molecules. In selected cases, complex sugars exist alone and unattached. Structurally, complex sugars are composed of individual saccharide building blocks, or monosaccharides, that may form linear or branched chains.

The location of the complex sugar determines the distinct function that it performs:

- *Sugars bound to the cell surface.* Complex sugars "coat" the surface of virtually all cells. Cell surface sugars are critical for proper cell function and may act alone or in conjunction with proteins to regulate cell growth, death or the future definition of a cell. In addition, in certain disease states, a cell's sugar coat changes, affecting how the cell perceives its environment and thereby responds to signaling molecules. For example, this can affect how cancerous cells proliferate and spread. Complex sugars at the surface of cells also influence the efficacy and side-effect profile of drugs.

- *Sugars present in the extracellular matrix, or between cells.* Complex sugars located between cells help cells communicate with one another to orchestrate complex biologic processes. Tissue generation, wound healing and immune response to viral infection are examples of biological processes regulated by sugars present in the extracellular matrix. Additionally, complex sugars between cells affect diseases, such as asthma and inflammatory bowel disease, by controlling the inflammation process.

- *Sugars attached to proteins.* Complex sugars coat proteins that are made by the cell. The sugar coat influences how long the protein remains in the body, where the protein goes and what activity it performs. The sugars that coat a protein thus "fine-tune" the protein's activity and provide an additional level of biological control.

Applications of Complex Sugars in Drug Discovery and Development

Understanding where sugars are found 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 develop drugs:

Complex sugar-based therapeutics. Complex sugars, either synthesized chemically or isolated from natural sources, can be used as therapeutic drugs. One prominent example is the heparin class of sugars, which exist as heterogeneous mixtures of complex sugar chains extracted from the lining of pig intestines. Heparins are used therapeutically to prevent blood clotting and represented approximately a $2.8 billion worldwide market in 2002. Other complex sugar-based drugs in development include chondroitins for neural injury and pectins for cancer.

Engineering sugars on therapeutics. There are three major drug classes that frequently have complex sugar coats: proteins (including antibodies), vaccines and antibiotics. Therapeutic proteins, the vast majority of which contain sugar coats, are a rapidly growing area of the pharmaceutical and biotechnology industries. Worldwide annual sales of therapeutic proteins are estimated to be

$30.3 billion. Altering the complex sugar coat of a protein can dramatically change the properties of a drug. For example, Amgen, Inc. modified its protein drug, Epogen®, by incorporating additional sugar groups to the protein creating a novel second generation anemia drug, Aranesp®, that has a decreased dosing schedule.

Complex sugars in small molecule and antibody development. The fields of genomics and proteomics have resulted in the identification of large numbers of genes and proteins. Understanding only DNA and proteins, however, provides incomplete information about the biological function of these potential drug targets. Identifying appropriate drug targets depends on understanding the sequential interaction of proteins in disease, known as disease pathways. Understanding the role of sugars, which can both activate and regulate these pathways, provides a more complete picture of biology and we believe can create 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, 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 to Developing Drugs Based on Complex Sugars

A number of challenges have inhibited the widespread analysis and application of complex sugars to drug development:

Structural complexity and information density. Deciphering the role of complex sugars in promoting or treating human diseases has been challenging given the density of information contained in complex sugars and the lack of sophisticated tools to interpret their information content. Complex sugars have far more information density than DNA and proteins. DNA is comprised of four different bases and proteins can contain 20 different amino acids. The DNA bases and amino acids can be combined to produce 256 possible four-unit DNA structures and 160,000 potential four-unit protein structures, respectively. In comparison, complex sugars, such as heparin, may contain as many as 48 different disaccharide units, resulting in approximately 5.3 million possible four-unit disaccharide combinations. In addition, while proteins and DNA exist only in linear forms, sugars can also exist in branched forms, adding structural complexity and information density.

Lack of amplification. DNA and proteins can be easily amplified, or duplicated, in larger quantities for analysis, facilitating simple manipulation and rapid identification of sequences. Complex sugars, however, cannot be amplified due to their structural diversity and the manner in which they are synthesized. Consequently, the analysis of complex sugars requires the development of novel, highly sensitive, analytical tools and technologies that can work with small quantities of material.

Heterogeneity. DNA and proteins can be isolated 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.

These limitations have made sugar-based drug research, discovery and development challenging, leading the National Institutes of Health, or NIH, to identify the study of sugars as a key field expected to shape the future of molecular and cellular biology and to devote significant financial resources to create the Consortium for Functional Glycomics.

Momenta Technology Solution

We have developed an integrated technology solution that addresses the challenges of creating drugs based on complex sugars. Our technology enables rapid, precise and comprehensive sequencing of complex sugars. Using proprietary enzymes or reagents, we break down structurally complex and information dense sugar chains, including those contained in complex mixtures, into measurable units. Our proprietary analytical techniques and expertise allow us to gather information regarding the components, structure and arrangement of the building blocks in the sugar chains. Our proprietary mathematical methods allow us to integrate the information we obtain from multiple sources into a specific, numerically derived solution describing the specific sugar sequence. The combined sensitivity of all of our analytical techniques allows us to work with very small quantities of material, avoiding the need for amplification.

The specific elements that make up our proprietary technology include the following:

- *Proprietary enzymes/reagents.* We have built a comprehensive library of recombinant enzymes and reagents which function like restriction enzymes and selectively cleave, or cut, complex sugars into distinct patterns to aid in our sequencing. By applying these enzymes and reagents to complex sugar sequences or mixtures, we gain specific knowledge about the basic saccharide units, or building blocks, which make up longer sugar chains as well as the sequence order of the units.

- *Sugar-based analytic techniques.* We have taken established analytic methods such as Matrix Assisted Laser Desorption Ionization-Mass Spectrometry, or MALDI-MS, nuclear magnetic resonance, or NMR, and capillary electrophoresis, or CE, and made proprietary modifications to each of these methods enabling improved analysis of complex sugars. These techniques provide critical information about the molecular weight, chemical identity and bonds between complex sugar units.

- *Mathematical methods for integrating data.* We employ patent-protected, mathematical methods that integrate the disparate information collected from various analytical techniques. These methods, allow us to interpret data and determine the specific sequences contained in complex sugar chains. These methods utilize a property encoded nomenclature that includes a hexadecimal coding system specifically designed to analyze the dense information content of complex sugars.

Our proprietary technology has enabled us to rapidly sequence and accurately verify complex sugars in a matter of minutes to hours—a process which previously took years. We apply our various proprietary techniques to a specific complex sugar sample to yield distinct structural information including the sample's molecular weight, composition of its saccharide units, specific linkages and other characteristics. For example, we believe we were the first to rapidly and accurately sequence complex sugar chains comprised of ten saccharide units, which can contain up to 255 million possible combinations. Our approach is to first measure the mass of the sugar using our proprietary MALDI-MS techniques. Through this mass analysis, we can determine the chain length and certain chemical structures of the sugar chain. We utilize various proprietary enzymes to break the sugar chain into smaller units to determine the sequence order of sugar building blocks. We can also apply our proprietary approaches to NMR to ascertain information about the manner in which various sugar building blocks are linked to one another. The various sources of data are integrated using our proprietary mathematical methods, thereby enabling a precise characterization, or sequencing, of the complete structure of a complex sugar chain.

Our technology has the following features:

- *Rapid and accurate sequencing.* Our technology enables rapid sequencing of complex sugars with a high level of accuracy. Previously, sequencing complex sugars containing six or eight saccharide

units, or building blocks, could take years and the accurate sequencing of longer complex sugars had never been accomplished. Our technology enables sequencing of these sugars in a matter of minutes to hours, and also allows us to sequence sugar chains longer than ten saccharide units.

- *Highly sensitive techniques.* Since complex sugars cannot be amplified, or duplicated, for analysis, we have developed techniques that facilitate the analysis of small quantities of biological samples. This enables us to access and analyze blood and tissue samples to identify and link specific sugar structures with their corresponding biological function.

- *Comprehensive analysis.* Despite the variability of complex sugars in composition and form, we can identify the detailed sequences and the complete chemical structure of complex sugars, not simply the basic underlying backbone of the sugar chain.

Applications of Momenta Technology

We plan to apply our technology to product development in three primary ways:

Enable generic versions of complex drugs through characterization. Many currently marketed drugs containing sugars have not been fully characterized, or sequenced, due to lack of available technology. These drugs include heparins, therapeutic proteins, vaccines and antibiotics. Our technology allows us to elucidate the precise sugar sequences contained in marketed, complex sugar-based drugs, including those structures that had not previously been described. To approve generic versions of branded products, the FDA requires data demonstrating that the generic product contains the same active ingredients as the branded product. The inability to analyze existing complex sugar-based drugs has made it difficult to obtain approval of generic versions of such drugs to date. We believe that the information obtained from our detailed analysis can be applied to develop technology-enabled generic versions of complex sugar-based marketed products.

Improve therapeutic products. We intend to use our technology to create proprietary drugs that represent improvements over currently marketed drugs by:

- *Rationally designing complex sugar structures.* We utilize our technology to rationally engineer heparin and protein drugs to improve their properties and address unmet medical needs. The engineering of sugars within drugs to date has been performed without a comprehensive understanding of the existing sugar structures. We believe that our ability to identify sugar structures, correlate them to biological activity and engineer these sugar structures will lead to improved drugs with enhanced clinical activity, reduced toxicity and optimal half-life. Our development candidate, M118, is a LMWH that has been engineered to possess an optimal 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 improvements in the delivery of a broad range of therapeutic protein drugs, including increased bioavailability, or the quantity and duration of time a drug is present in the blood stream, improved safety and the ability to deliver larger drugs. We are currently applying this technology to develop pulmonary formulations of interferon-beta, erythropoietin, insulin and HGH.

Discover novel drugs. We intend to apply 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. Research has shown that malfunctions in sugar production and the resulting abnormal sugar structures play a fundamental role in diseases, including cancer, cardiovascular disease, Alzheimer's disease, inflammatory disease and viral infection. Our current focus on drug discovery is in

oncology, where we believe we can apply our technology to develop drugs that act through novel mechanisms. Based on our recent research, we have shown that sugars can both decrease the growth and increase the death of cancer cells.

Our Business Strategy

Our objective is to become a leading biotechnology company by applying our understanding of complex sugars and our proprietary technologies to drug discovery, development and commercialization. The key elements of our strategy are to:

- *Maximize the commercial potential of M-Enoxaparin and leverage our analytic capabilities to commercialize other near-term opportunities.* We are currently focused on developing, filing a regulatory application, attaining regulatory approval and bringing M-Enoxaparin, our technology-enabled generic version of Lovenox, to market. We believe that this near-term opportunity does not require extensive human clinical studies or the typical investment required for new drugs. If successfully developed and approved by regulatory authorities, we believe M-Enoxaparin could enable us to realize significant commercial value on a compressed time line with comparatively limited capital investment. We plan to capitalize on this and other near-term revenue opportunities which apply our technology to foster long-term growth and to partially fund our novel drug discovery and development programs.

- *Advance our improved development product opportunities into clinical trials.* We leverage our characterization capabilities and our understanding of the biological activity of specific sugar structures to engineer improvements to marketed products. M118 was engineered to include certain sugar sequences which we believe will offer key efficacy and safety improvements over current therapies. We utilize our knowledge about sugars that can transport large drugs across mucosal membranes to develop pulmonary formulations of therapeutic proteins. We believe these novel formulations offer improved dose administration over existing therapies. By advancing these product opportunities into clinical trials over the next several years, we believe that we will build a diversified product pipeline.

- *Leverage our proprietary technology and apply our understanding of sugars to create novel therapeutics to address critical unmet needs.* Our understanding of the role of complex sugars in cellular processes and disease enables us to design drugs based on unexploited or completely new mechanisms. Our research is focused on diseases with critical unmet medical needs, such as oncology, immunology and inflammation.

- *Enhance our internal development programs through selective partnering.* We intend to internally develop products from our pipeline that fit with our therapeutic areas of expertise and which we believe we can develop and commercialize successfully on our own. We may seek joint development and marketing partnerships for products that require a significant capital investment or specialized expertise that may be better provided by pharmaceutical companies. In addition, we will seek to out-license certain opportunities that do not fit within our strategy.

- *Establish development capabilities and sales and marketing capabilities focused on key in-hospital markets.* We intend to build internal product development and sales and marketing capabilities to become a fully-integrated biotechnology company. 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. The initial focus for our internal development will likely be oncology and cardiovascular disease.

Product Pipeline

Overview of Product Pipeline

Our product pipeline consists of technology-enabled generic versions of marketed, complex, sugar-based drugs, new compounds that are improved versions of existing products and novel discovery candidates. The pipeline is summarized in the table below:

Drug Candidate(s)	Therapeutic Area	Current Stage of Development
M-Enoxaparin*	Thrombosis	Pre-ANDA
M-Dalteparin	Thrombosis	Development
M118	Cardiovascular Disease	Preclinical
Pulmonary Insulin	Diabetes	Preclinical
Pulmonary HGH	Growth Hormone Deficiency	Preclinical
Pulmonary Interferon-beta	Multiple Sclerosis	Discovery
Pulmonary Erythropoietin	Anemia	Discovery
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 distributed worldwide by Aventis and is also known outside the United States as Clexane® and Klexane®. Lovenox is the most widely-prescribed LMWH in the world used for the prevention and treatment of DVT and treatment of ACS. In 2003, Aventis reported worldwide sales of Lovenox of approximately $1.9 billion, and analysts project sales to exceed $3.0 billion in 2008. Lovenox is a heterogeneous mixture of complex sugar chains that has not been adequately analyzed to date. Aventis, in a Citizen Petition filed with the FDA in February 2003 and in a supplement filed in February 2004, 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. 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 a generic version of Lovenox. We intend to file an ANDA, or other regulatory application as determined by the FDA, in the next 12 months.

Market Overview. DVT affects approximately 2.0 million people in the United States each year, approximately 600,000 of whom experience potentially fatal pulmonary embolisms. In addition, more than 20 million people in the United States annually undergo major surgeries or have restricted mobility due to medical illnesses, which place them at risk for DVT. Each year, approximately 1.3 million patients in the United States are also diagnosed with ACS. ACS includes several diseases 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. All diseases in ACS are associated with the formation of blood clots.

According to industry forecasts, the LMWH class of drugs is projected to grow from annual sales of $2.5 billion worldwide today to annual sales of over $3.6 billion by 2010. Lovenox is the leading LMWH product, with the broadest set of approved indications of any of the LMWHs currently marketed. Aventis reported worldwide sales of Lovenox of approximately $1.9 billion in 2003, with approximately $1.2 billion coming from the United States market alone. Fragmin (Pfizer) and Fraxiparine® (Sanofi-Synthelabo) are the next closest competitors to Lovenox. In 2002, worldwide sales of Fragmin were $270 million, and in 2003, worldwide sales of Fraxiparine were $361 million. Analysts project that Lovenox will remain the dominant LMWH product, growing to over $3.0 billion in annual sales by 2008, which represents over 83% of the estimated LMWH market.

Aventis has publicly disclosed its plans to secure Lovenox's position as the leading injectable anticoagulant by seeking approval for additional indications in ACS, in which unfractionated heparin, or UFH, is currently the leading drug. In addition, Aventis is seeking to both grow existing and secure new indications for the prevention and treatment of DVT and pulmonary embolism. These new indications may lead to substantial sales growth, especially in the United States, where Lovenox currently dominates the LMWH market.

Lovenox composition. Lovenox is derived from UFH, which is a naturally occurring sugar mixture derived from the lining of pig intestines. UFH exists as a complex, heterogeneous mixture of sugar chains of varying length and varying sequence. Lovenox is made by chemically cutting these longer UFH chains into shorter chains, which are also heterogeneous 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. 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 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. We believe our technology enables a detailed description of the Lovenox mixture.

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."

We believe the many sugar structures in Lovenox contribute to the drug's various biological activities and thus represent components of the active ingredients by the FDA's definition. There is significant evidence that specific structures contained in heparins, such as Lovenox, contribute to various biological activities beyond the current description of anticoagulation. Specifically, it has been shown in scientific literature that heparins bind to many biologically important factors. These structures are not described by molecular weight distribution or anti-Xa and anti-IIa activity measures. Through our technology, we have the ability to analyze the Lovenox mixture and demonstrate that a generic product has the same active ingredients as Lovenox.

While Aventis publicly acknowledges that they have not characterized large portions of Lovenox, they have been able to analyze certain additional chemical features of the product. Through their analysis, Aventis has stated that it is possible to make an "alternative LMWH" that possesses the same molecular weight distribution and *in vitro* anti-Xa and anti-IIa activity as Lovenox, but contains different chemical structures, making it chemically distinct from Lovenox. They have shown that these chemical differences can result in changes in biological activities, which are relevant to the efficacy of

the product. These changes impact biological processes that are important in clot formation and ACS, such as the growth of smooth muscles in blood vessels and the activity of factors, such as fibroblast growth factor, that can help to increase blood flow through growing new blood vessels. They have also shown that these structures can potentially affect anticoagulation parameters that are not measured by *in vitro* anti-Xa and anti-IIa activity alone and may affect both efficacy and bleeding risks associated with the product.

Based on evidence that multiple structures in Lovenox contribute to its overall activity, we believe any regulatory application for generic enoxaparin must demonstrate that it has the same active ingredients as Lovenox, thereby enabling the FDA to approve the application. We believe this detailed analysis is required to assure the equivalent efficacy and safety of the generic product to Lovenox.

M-Enoxaparin development strategy. Through the application of our technology, we believe 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 be pharmaceutically equivalent and 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.

We plan to manufacture and provide the appropriate stability and reproducibility data on multiple batches of M-Enoxaparin and demonstrate that our proposed product has the same active ingredients and is therapeutically equivalent to Lovenox. Detailed information on the reproducibility and validation of our methodology, such as techniques and assays, will be presented to the FDA, in accordance with FDA regulations and requirements. In addition, all activities will be conducted in accordance with cGMP.

To date, we have successfully accomplished the following:

- *Analysis of Lovenox.* We have obtained and analyzed multiple batches of commercially available Lovenox, all within expiry dating. This analysis has allowed us to develop criteria for comparing our own version of enoxaparin to the branded product.
- *Process development.* We believe we have identified a process that will allow us to produce a generic enoxaparin which has the same active ingredients as Lovenox.
- *Manufacturing capabilities.* Through third-party contract manufacturers, we are establishing a supply chain to manufacture drug substance and drug product.
- *Sandoz agreement.* We have entered into an exclusive collaboration agreement with Sandoz to jointly develop and commercialize M-Enoxaparin.

Prior to submitting a regulatory application, we intend to complete our scale up of the bulk drug substance, fill the drug substance into syringes and vials to create the final drug product presentations and test stability of the finished drug substance and product lots.

Legal matters. Currently, Aventis has listed two patents for Lovenox in the Orange Book, the FDA's listing of approved drug products. According to Aventis, United States Patent No. 4,692,435 expires December 24, 2004, which is prior to the date we anticipate we will commercialize M-Enoxaparin, and Patent No. 5,389,618, or the '618 patent, expires on February 14, 2012. We are currently evaluating our options with respect to the '618 patent.

It is typical for the manufacturer of the branded product to initiate litigation against generic competitors seeking FDA approval to commercialize their products prior to expiration of the branded

company's patents. Aventis has sued both Amphastar and Teva for patent infringement based upon their respective generic enoxaparin filings, and we anticipate Aventis may also initiate legal proceedings against us following our regulatory filing. There is also the possibility that other third party patent infringement claims will be brought against us. 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 Aventis, and certain other claims, in each case which relate to the development and commercialization of our generic enoxaparin product. Sandoz may offset certain of these costs against the profit-sharing amounts, the royalties and the commercial milestone payments they may be required to make to us.

M-Dalteparin

We intend to develop a technology-enabled generic version of Fragmin (dalteparin), the second largest selling LMWH product in the United States. Fragmin is currently marketed by Pfizer in the United States and Europe and Kissei Pharmaceutical Co, Ltd. in Japan. The product is indicated for the prevention of DVT following abdominal and hip replacement surgeries and selected indications in ACS. In 2002, Fragmin had worldwide sales of $270 million, representing approximately 11% of the LMWH market. Sales in the United States were approximately $87 million in 2002.

Similar to Lovenox, Fragmin is currently described by molecular weight distribution, anti-Xa activity and anti-IIa activity. We believe that additional criteria are necessary to fully demonstrate the presence of the same active ingredients to support the filing of a generic application.

We expect M-Dalteparin will leverage the same technical, regulatory and commercial strategy as M-Enoxaparin. 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.

Our plan is to submit a regulatory application for M-Dalteparin in the next 18 to 24 months. Over the next year, we expect to analyze multiple commercial batches of Fragmin and then develop a manufacturing process to produce a therapeutically equivalent product. The Orange Book patent listed for Fragmin will expire in January 2005, prior to our plans for commercialization.

Other Opportunities

Over the next few years, many existing therapeutic protein drugs, or biologics, containing sugars which were approved as Biological Licensing Applications, or BLAs, will lose patent and marketing exclusivity protection. Developing generic versions of these drugs will prove challenging because there is significant scientific, regulatory and legal debate about the ability and precedent for developing equivalent versions of these drugs given their inherent complexity. As sugars play a critical role in many of these protein-based products, we may seek to apply our technology to create technology-enabled generic versions of these marketed products, leveraging strategies similar to that of M-Enoxaparin. These product opportunities are longer term because there is uncertainty related to the regulatory approval process for generic biologics.

Improved Development Products

We are developing proprietary drug candidates based upon our sugar sequencing technology and expertise. We intend to apply our technology to improve existing drugs and develop novel drugs. Our development opportunities include:

- M118, our rationally designed LMWH for the treatment of ACS;
- a sugar-mediated technology that we designed to improve the non-invasive delivery of therapeutic proteins such as interferon-beta, erythropoietin, insulin and HGH; and

- capabilities that we designed to enable engineering of complex sugars on therapeutic proteins, such as anti-tumor necrosis factor, or anti-TNF drugs, to modify certain biological activities, improve efficacy, reduce side effects and modify dosing frequency of protein drugs.

M118

M118 is a LMWH that we rationally designed to provide improved anti-clotting activity and flexible administration to treat patients with ACS. M118 is a potent inhibitor of multiple factors in the blood that lead to clot formation, whereas currently marketed LMWHs primarily inhibit a single factor contributing to clot formation. This is critical in ACS patients who have an existing clot in a coronary artery because M118 prevents not only the formation of new clots, but also the extension of the existing clot.

Heparins, including UFH and LMWHs, are used as baseline therapy in ACS, and if required, in subsequent invasive procedures. The selection of a particular heparin is dictated by efficacy, predictability, safety and the ability to monitor the level of and reverse anticoagulation. Due to M118's beneficial biological activities and flexible administration, we believe M118 could be the baseline heparin of choice to treat patients diagnosed with ACS and to treat those patients who subsequently require angioplasty or coronary bypass graft surgery, or CABG. Angioplasty is a procedure involving the deployment of a device inside an obstructed artery to restore normal blood flow. CABG is a procedure involving the bypass of a blocked coronary artery with a grafted new artery.

Market overview. ACS includes several diseases ranging from unstable angina, which is characterized as chest pain at rest, to acute myocardial infarction, or heart attack, which is caused by a complete blockage of a coronary artery. Approximately 37% of the 1.3 million patients that are diagnosed with ACS in the United States annually respond favorably to initial medical management with anti-clotting agents, such as UFH or LMWH. The remaining patients who do not respond well to this treatment will typically require additional interventional or surgical procedures, such as 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. There are no LMWHs currently approved for use in either angioplasty or CABG.

The decision regarding which anti-clotting agent is initially administered depends upon the physician's assessment of the patient's anticipated treatment path. LMWH has demonstrated superior efficacy, or effectiveness, over UFH in the initial clinical setting where patients are managed medically. LMWHs are easier to administer, as they may be injected subcutaneously, as opposed to UFH, which must be administered intravenously. Existing LMWHs, however, have undesirable properties that limit their use in those situations where the patient might require angioplasty or CABG. LMWHs cannot be monitored by standard laboratory clotting tests. If a patient initially receives LMWH in the emergency room and subsequently requires angioplasty, the physician will be unable to quickly determine the degree of anticoagulation previously attained. Consequently, administering too little or too much anticoagulant during the procedure may result in stroke or serious bleeding complications. The ability to monitor UFH thus makes UFH the anti-clotting drug of choice in virtually all patients undergoing angioplasty, even though it has relatively unpredictable biological activities. In addition, LMWHs are not suitable drugs for CABG procedures because their anti-clotting activity cannot be reversed. This is particularly problematic in CABG patients who typically receive protamine sulfate following invasive surgery to reverse the anti-clotting activity of UFH and restore normal clotting mechanisms. Since the physician cannot always determine initially whether a patient will require medical management, angioplasty or CABG, the default anticoagulant chosen for patients entering the emergency room is often UFH.

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 sugar sequences responsible for anti-clotting activity. Using our proprietary enzymes to

precisely cut the longer chains of UFH in specific locations, we developed a drug candidate specifically designed to address the unmet medical needs of anticoagulation therapy in ACS. By choosing M118 as the primary baseline therapy for ACS patients, we believe physicians will be able to deliver safer, more efficacious and consistent therapy, while retaining the flexibility to make the appropriate clinical care treatment decisions for all ACS patients, regardless of the need for medical management, angioplasty or CABG.

Our preclinical animal studies have demonstrated potential benefits of M118 over UFH and other LMWHs. These potential benefits include:

- *Increased efficacy.* Our preclinical studies have demonstrated that M118 is a potent inhibitor of clot formation and extension. 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. Results from early animal tests, however, are not always duplicated when product candidates are tested in humans.

- *Reversibility.* We have demonstrated that the anti-clotting effects of M118 are fully reversible in animals by administering protamine sulfate, the standard drug used to reverse anticoagulant activity. In preclinical studies, we observed that M118 required lower doses of protamine sulfate than UFH to rapidly reverse anti-clotting effects, which is important due to the potential adverse effects associated with protamine sulfate, including severe allergic reaction and low blood pressure. There are no currently approved drugs that counteract the bleeding in a patient treated with a conventional LMWH. Results from early animal tests, however, are not always duplicated when product candidates are tested in humans.

- *More predictable response.* The anti-clotting effect of M118 is more predictable than other LMWHs and UFH due to the relatively uniform structure of the compound. This predictable response may allow physicians to carefully target an appropriate level of anticoagulation without risk of overdose, which can lead to excessive bleeding.

- *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. We believe physicians performing angioplasty and CABG will be able to accurately monitor the level of anti-thrombotic activity of M118 during these procedures. 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.

M118 is an early preclinical product candidate and, therefore, we have not yet demonstrated statistically significant differences in our animal experiments due to the small number of animals treated.

Product development status. M118 is currently in preclinical development. We are working with a third-party manufacturer to produce both our proprietary enzyme and drug substance required in the manufacturing process for M118. The UFH starting material has been obtained from a qualified manufacturer.

We are currently increasing our manufacturing capabilities to produce sufficient quantities of the drug substance required to develop M118 through the end of Phase I clinical trials. We anticipate that the manufacturing activities will be completed in the first half of 2004.

We intend to submit an IND to the FDA prior to the end of the first half of 2005 and 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.

Sugar-Mediated Non-Invasive Delivery

We have identified that sugars facilitate the transport of molecules, including proteins, across mucosal membranes, leading to high levels of bioavailability. Through our sequencing capabilities, we have identified sugars that regulate this transport process. These sugars can be mixed with a variety of protein drugs enabling their delivery across mucosal membranes into the blood stream. We have demonstrated in our animal studies that the sugar transport process is rapid and fully reversible within a matter of minutes, though results from animal tests are not always duplicated when product candidates are tested in humans. In addition, these early preclinical studies did not include adequate numbers of animals to demonstrate statistical significance.

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, 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 the pulmonary delivery of therapeutic proteins, where bioavailability has been a challenge. Our initial proof-of-concept, preclinical studies designed to test the delivery of insulin and HGH through the lung, have been completed. 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. In addition, our studies with pulmonary insulin have demonstrated that the insulin remains effective at lowering blood glucose levels.

Market opportunity. Based upon industry reports, the estimated market size of the largest therapeutic protein markets, which specifically includes anemia, diabetes, multiple sclerosis, growth hormone deficiency and rheumatoid arthritis, represented a $16.0 billion opportunity in 2001 and is estimated to grow to approximately $30.0 billion in 2010. We believe the largest opportunities for pulmonary formulations of protein drugs are for interferon-beta, also known as Avonex® and Rebif®, which is used to treat multiple sclerosis, and erythropoietin, also known as Epogen® and Procrit®, which is used to treat anemia. We are currently exploring co-development opportunities for our pulmonary insulin and pulmonary HGH programs.

We are focusing our initial internal development efforts on the following product opportunities:

- *Pulmonary interferon-beta.* We have begun preclinical testing of pulmonary interferon-beta in various animal inhalation models, including initiating bioavailability studies. We intend to continue our preclinical and formulation activities through 2004.

- *Pulmonary erythropoietin.* We plan to initiate early development activities, including formulation and preliminary safety and bioavailability studies, in the second half of 2004.

- *Pulmonary insulin.* We have completed our preliminary evaluation of pulmonary insulin in safety, efficacy and bioavailability studies, demonstrating five times greater bioavailability as compared with other technologies, and have observed no adverse findings.

- *Pulmonary HGH.* We have conducted preliminary evaluations of HGH in animal models and have demonstrated a ten-fold increase in bioavailability as compared with other technologies in comparable models.

Potential benefits of sugar-mediated pulmonary delivery. We believe our pulmonary delivery of therapeutic proteins has distinct advantages over current technologies. Some of these advantages include:

- *Upper airway delivery.* Existing technologies target delivery of small drug particles to the deep lung. Our technology, in contrast, delivers larger drug particles to the upper lung. The upper lung has more efficient clearance mechanisms and is better able to eliminate excess material

than the deep lung, which may result in reduced toxicity or decreased risk of developing an immune response from an inhaled product. We have demonstrated in animals that approximately 99% of an inhaled insulin dose is rapidly carried into the blood stream or cleared. We have not observed undesired local effects on the lung tissues in gross pathology and histology studies.

- *Delivery of larger therapeutic proteins.* Technologies currently being evaluated in clinical trials do not enable efficient delivery of larger proteins. We believe our technology will enable us to efficiently deliver larger proteins to the upper lung, in comparison with other technologies that are limited to delivery of smaller proteins, such as insulin.

- *Natural sugar formulations.* Our pulmonary delivery formulations are comprised of naturally occurring complex sugar sequences that are mixed with therapeutic proteins. We do not modify the proteins to be delivered in the formulation process or make any structural changes to the protein that might cause an unwanted immune response. This allows us to deliver a currently marketed drug by altering the formulation rather than chemically modifying the active ingredient.

- *Higher bioavailability.* We have demonstrated significantly greater levels of bioavailability of therapeutic proteins than levels reported by others. For example, we have consistently achieved bioavailability levels greater than 80% with pulmonary insulin in our animal models. This higher level of bioavailability permits smaller quantities of drugs to be administered relative to other inhaled delivery methods. Higher bioavailability results in less variability in patient dosing and more cost efficient pulmonary delivery of established injectable proteins.

- *Rapid onset of action.* Our preclinical studies demonstrate that therapeutic proteins quickly enter the blood stream when administered through the lung.

Capabilities that Enable Engineering of Complex Sugars on Therapeutic Proteins

Our analytical and sequencing technologies can also be applied to characterize and re-engineer sugars that exist on the surface of therapeutic proteins. We can engineer new forms of sugars by determining how the manufacturing process changes the distribution of sugars present on the protein, thereby changing biological properties. Altering the complex sugar coat of a protein can potentially improve efficacy and tissue targeting, reduce negative side effects, such as allergic reactions and modify the dosing frequency of the protein drugs. We have also licensed technology that can add or change the sugar units attached to proteins.

We believe our technology will allow us to efficiently engineer desired modifications to existing proteins, to address significant unmet needs and capitalize on a number of potential product opportunities. For example, unmet needs within chronic diseases such as rheumatoid arthritis, which is treated by anti-TNF agents, include reductions in the dose frequency and increased efficacy among existing therapies. We believe we may be able to affect these multiple properties through the isolation, quantification and systematic modification to the sugar structures on these proteins.

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 signaling between proteins in pathways to fundamentally affect basic biology. We believe the role of sugars in disease progression can be exploited to discover novel therapeutics for a range of diseases. We believe a drug discovery program that incorporates both protein and sugar biology will result in the discovery of many new mechanisms that can be targeted with small molecule or antibody drugs. We also believe it will be possible to develop drugs made from sugars 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, regulating

tumor growth and playing a role in tumor invasion and metastasis. As normal cells change into cancerous cells, the sugar coats on their cell surfaces also 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 studies that these sugars selectively inhibit proliferation of cancer cells and increase apoptosis, or cell death. Finally, a better understanding of the role that sugars play in modulating protein pathways can aid in the understanding of cancer mechanisms and the discovery of new small molecule and antibody drugs.

Sugar-based drugs. We have identified sugar sequences that have demonstrated potent anti-tumor effects in animals, as compared with control groups. Results from early testing in animals, however, are not always duplicated when product candidates are tested in humans. 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 of prostate cancer. We are evaluating whether to devote resources to further pursue development of sugar-based diagnostics.

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 agree 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 have granted to Sandoz the right to negotiate additional rights under certain circumstances. Sandoz has exercised an exclusive right to negotiate an exclusive license to develop and commercialize injectable enoxaparin outside of the United States. We will negotiate in good faith a definitive agreement on terms generally consistent with the agreement, but with certain specified variations. If we and Sandoz have not entered into a license agreement by November 1, 2004, then we may arrange to work with third parties to develop or commercialize injectable enoxaparin, provided that we give Sandoz a right of first refusal with respect to such activities. 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. If Sandoz does not exercise its negotiation right, or if it does exercise its negotiation right for any of these opportunities, but we and Sandoz do not execute a definitive agreement within a specified time frame, then, for a specified time, we are permitted to enter into a transaction for such opportunity with a third party, provided that, under certain circumstances, the terms which we give to that third party can be no less favorable, taken as a whole, to us than the terms last offered to Sandoz. If we do not enter into a transaction with a