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As filed with the Securities and Exchange Commission on April 16, 2004.

Registration No. 333-113522

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

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Amendment No. 1  
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**  
(State or other jurisdiction of  
incorporation or organization)

**2836**  
(Primary Standard Industrial  
Classification Code Number)

**04-3561634**  
(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:

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**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.

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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.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated \_\_\_\_\_, 2004

## Shares

# MOMENTA



## Common Stock

Momenta Pharmaceuticals, Inc. is offering \_\_\_\_\_ 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 \$ \_\_\_\_\_ and \$ \_\_\_\_\_ 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 \_\_\_\_\_ 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**

**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.

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## 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. The FDA, however, has not yet established a regulatory standard for generic versions of complex drugs, such as LMWHs. If the FDA does not establish a standard for therapeutic equivalence of generic versions of complex drugs, or if we fail to demonstrate that we meet the criteria once established, 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. These patents expire on December 24, 2004 and February 14, 2012. 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 approximately six to 12 months after our M-Enoxaparin filing. Pfizer has listed one patent for Fragmin in the Orange Book which expires January 4, 2005, prior to our plans for commercialization.

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### 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 quarter 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.

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### 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 December 31, 2003, we had an accumulated deficit of approximately \$15.6 million. We recognized net losses of \$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. Our ability to commercialize these products 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](http://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.

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### THE OFFERING

Common stock offered	shares
Common stock to be outstanding after this offering	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 March 1, 2004.

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

- 797,605 shares of common stock issuable upon the exercise of outstanding stock options as of March 1, 2004 at a weighted average exercise price of \$0.38 per share;
- an aggregate of 3,494,872 shares of common stock that will be 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
- 12,500 shares of common stock issuable upon the exercise of an outstanding warrant that will remain outstanding after this offering at an exercise price of \$2.87 per share.

Unless otherwise noted, the information in this prospectus assumes that the underwriters do not exercise their over-allotment option, reflects the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 11,730,012 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.

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## 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 December 31, 2003 into an aggregate of 9,117,316 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,	
	2002	2003
	Restated*	

(In thousands, except per share information)

<b>Statements of Operations Data:</b>			
Collaboration revenue	\$	—	\$ 1,454
<b>Operating expenses:</b>			
Research and development		206	5,348
General and administrative		167	4,082
Total operating expenses		373	9,430
Loss from operations		(373)	(7,976)
Interest income		2	74
Interest expense		—	(43)
Net loss		(371)	(7,945)
Dividends and accretion to redeemable convertible preferred stock		(22)	(1,899)
Net loss attributable to common stockholders	\$	(393)	\$ (9,844)
Basic and diluted net loss attributable to common stockholders per common share	\$	(8.63)	\$ (6.42)
Weighted average shares outstanding—basic and diluted		45	1,532
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share			\$ (0.95)
Unaudited pro forma weighted average shares outstanding—basic and diluted			8,373

\* See Note 17 to our financial statements, page F-26.

The pro forma balance sheet data gives effect to the sale of shares of our Series C redeemable convertible preferred stock on February 27, 2004. The pro forma as adjusted balance sheet data gives further effect to our sale of \_\_\_\_\_ shares of common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ 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 into an aggregate of 11,730,012 shares of common stock upon the completion of this offering.

As of December 31, 2003

Actual	Unaudited Pro Forma	Unaudited Pro Forma As Adjusted
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(In thousands)

<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$	4,613	\$ 25,013
Short-term investments		7,994	7,994
Working capital		13,044	33,444
Total assets		16,084	36,484

Line of credit obligation—net of current portion	372	372
Redeemable convertible preferred stock	27,225	47,625
Accumulated deficit	(15,629)	(36,008)
Total stockholders' equity (deficit)	(13,779)	(13,779)

## 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 December 31, 2003, our accumulated deficit was approximately \$15.6 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. Depending upon a complex analysis of a variety of legal and commercial factors, our collaborator, Sandoz, may in certain circumstances, including upon expiration of the 30-month automatic stay on the FDA's ability to grant final approval of an ANDA, elect to market M-Enoxaparin, after FDA approval, even though litigation is still pending. This could be before any court decision or while an appeal of a lower court decision is pending. 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. 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.

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***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;

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- 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.

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***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.

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**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.

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***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.

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***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.

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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 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. 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.

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### **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 \$ \_\_\_\_\_ per share, based on an assumed initial public offering price of \$ \_\_\_\_\_ per share. Further, investors purchasing common stock in this offering will contribute approximately \_\_\_\_\_ % of the total amount invested by stockholders since our inception, but will own only approximately \_\_\_\_\_ % 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 March 1, 2004, options to purchase 797,605 shares of common stock at a weighted average exercise price of \$0.38 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. 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 % of our outstanding common stock, or % 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 \_\_\_\_\_ shares of common stock based on the number of shares outstanding as of March 1, 2004. This includes the \_\_\_\_\_ shares that we are selling in this offering, which may be resold in the public market immediately. The remaining \_\_\_\_\_ shares, or \_\_\_\_\_ %

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
shares, or _____ %	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.
shares, or _____ %	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 14,532,246 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 \_\_\_\_\_ shares of common stock that are authorized for issuance under our stock plans, employee stock purchase plan and outstanding stock options. As of March 1, 2004, 797,605 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.

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## USE OF PROCEEDS

We estimate that our net proceeds from the sale of \_\_\_\_\_ shares of common stock in this offering will be approximately \$ \_\_\_\_\_ million, assuming an initial public offering price of \$ \_\_\_\_\_ 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 \$ \_\_\_\_\_ 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 \$ \_\_\_\_\_ to \$ \_\_\_\_\_ to develop M-Dalteparin through the filing of an ANDA; and
- the development of improved product candidates, including using approximately \$ \_\_\_\_\_ to \$ \_\_\_\_\_ to develop M118 through Phase I and Phase II clinical trials and \$ \_\_\_\_\_ to \$ \_\_\_\_\_ 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.

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## CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2003:

- on an actual basis;
- on a pro forma basis, giving effect to the sale of 2,612,696 shares of Series C redeemable convertible preferred stock, at a per share price of \$7.8463, on February 27, 2004; and

- on a pro forma as adjusted basis to reflect further (a) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 11,730,012 shares of common stock upon the closing of this offering, and (b) the issuance and sale of \_\_\_\_\_ shares of common stock upon completion of this offering at an assumed initial public offering price of \$ \_\_\_\_\_ 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 December 31, 2003		
Actual	Unaudited Pro Forma	Unaudited Pro Forma As Adjusted
(In thousands)		
Cash and cash equivalents and short-term investments	\$ 12,607	\$ 33,007
Line of credit obligation—net of current portion	372	372
Redeemable convertible preferred stock, \$0.01 par value per share; 10,000,000 shares authorized actual and 12,000,000 shares authorized pro forma, no shares authorized pro forma as adjusted; 9,117,316 shares outstanding actual, 11,730,012 shares outstanding pro forma and no shares outstanding pro forma as adjusted	27,225	47,625
Stockholders' equity (deficit):		
Common stock, par value \$0.0001 per share; 20,000,000, 30,000,000 and 100,000,000 shares authorized actual, pro forma, and pro forma as adjusted, respectively; 3,252,193 shares outstanding actual and pro forma and _____ shares outstanding pro forma as adjusted	—	—
Preferred stock, par value \$0.01 per share; no shares authorized actual and pro forma, 5,000,000 shares authorized pro forma as adjusted; no shares outstanding actual, pro forma and pro forma as adjusted	—	—
Additional paid-in capital	4,961	25,340
Accumulated other comprehensive loss	(6)	(6)
Due from officer	(71)	(71)
Deferred compensation	(3,034)	(3,034)
Accumulated deficit	(15,629)	(36,008)
Total stockholders' equity (deficit)	(13,779)	(13,779)
Total capitalization	\$ 13,818	\$ 34,218

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The above data excludes:

- 805,230 shares of common stock issuable upon exercise of options outstanding as of December 31, 2003 with a weighted average exercise price of \$0.37 per share;
- an aggregate of 3,494,872 shares of common stock that will be reserved for future issuance under our 2004 stock incentive plan and our 2004 employee stock purchase plan; and
- 12,500 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 \$2.87 per share.

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## DILUTION

Our historical net tangible book value as of December 31, 2003 was \$(13.8) million, or \$(4.24) per share, based on 3,252,193 shares of common stock outstanding as of December 31, 2003. 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 December 31, 2003 was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share, based on \_\_\_\_\_ 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 \_\_\_\_\_ shares of common stock in this offering, at an assumed initial public offering price of \$ \_\_\_\_\_ per share, less estimated underwriting discounts and commissions and offering expenses payable by us and our sale of 2,612,696 shares of Series C redeemable convertible preferred stock, our pro forma net tangible book value as of December 31, 2003 would have been \$ \_\_\_\_\_ per share. This represents an immediate increase in pro forma net tangible book value per share of \$ \_\_\_\_\_ to existing stockholders and immediate dilution in pro forma net tangible book value of \$ \_\_\_\_\_ 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	\$
Historical net tangible book value per share at December 31, 2003	\$ (4.24)
_____	
Increase per share attributable to the conversion of redeemable convertible preferred stock	
_____	
Pro forma net tangible book value per share at December 31, 2003	
Increase per share attributable to new investors	
_____	
Pro forma net tangible book value per share after the offering	\$
_____	
Dilution of net tangible book value per share to new investors	\$
_____	

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

The following table summarizes the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid by our existing stockholders, by new investors in this offering, before deduction of the underwriting discount and commissions and other expenses of the offering:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders		%		%	\$
New investors					
_____					
Total		%		%	
_____					

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The share data in the table above is based on shares outstanding as of December 31, 2003 and excludes:

- 805,230 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2003 at a weighted average exercise price of \$0.37 per share;
- an aggregate of 3,494,872 shares of common stock that will be 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
- 12,500 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 \$2.87 per 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 \_\_\_\_\_ % 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 \_\_\_\_\_ or approximately \_\_\_\_\_ % of the total number of shares of our common stock outstanding after this offering.

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## 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 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 December 31, 2003 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,	
		2002	2003
		Restated*	
(In thousands, except per share information)			
<b>Statements of Operations Data:</b>			
Collaboration revenue	\$ —	\$ —	\$ 1,454
Operating expenses:			
Research and development	206	2,174	5,348
General and administrative	167	2,712	4,082
Total operating expenses	373	4,886	9,430
Loss from operations	(373)	(4,886)	(7,976)
Interest income	2	17	74
Interest expense	—	—	(43)
Net loss	(371)	(4,869)	(7,945)
Dividends and accretion to redeemable convertible preferred stock	(22)	(520)	(1,899)
Net loss attributable to common stockholders	\$ (393)	\$ (5,389)	\$ (9,844)
Basic and diluted net loss attributable to common stockholders per common share	\$ (8.63)	\$ (7.29)	\$ (6.42)
Weighted average shares outstanding—basic and diluted	45	739	1,532
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share			\$ (0.95)
Unaudited pro forma weighted average shares outstanding—basic and diluted			8,373

The pro forma balance sheet data gives effect to the sale of shares of our Series C redeemable convertible preferred stock on February 27, 2004.

	As of December 31,			Unaudited Pro Forma December 31, 2003
	2001	2002	2003	
	Restated*			
(In thousands)				
<b>Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 181	\$ 1,471	\$ 4,613	\$ 25,013
Short-term investments	—	—	7,994	7,994
Working capital	(128)	633	13,044	33,444
Total assets	(184)	2,500	16,084	36,484
Line of credit obligation—net of current portion	—	—	372	372
Redeemable convertible preferred stock	22	6,427	27,225	47,625
Accumulated deficit	(396)	(5,785)	(15,629)	(36,008)
Total stockholders' deficit	(148)	(4,831)	(13,779)	(13,779)

\* See Note 17 to our financial statements, page F-26.

## 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 revenue for the year ended December 31, 2003 was \$1.5 million, 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 December 31, 2003, we had an accumulated deficit of \$15.6 million. We recognized net losses of \$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

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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. All of our revenue to date has been derived 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.

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### **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 reimbursable 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**

### **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 paid for research and development services and other reimbursable costs. We had no revenues in Fiscal 2002 or 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.

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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.

<b>Research and Development Program</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>
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 no borrowings and no interest expense in Fiscal 2001 or 2002.

## **Liquidity and Capital Resources**

We have financed our operations since inception primarily through the private placement of equity securities. As of December 31, 2003, we have received net proceeds of \$25.0 million from the issuance of redeemable convertible preferred stock. At December 31, 2003, we had \$12.6 million in cash, cash equivalents and short-term investments. In February 2004, we sold an additional 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 will be recognized as a dividend in the first quarter of 2004.

Net cash used in operating activities was \$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 \$8.5 million for Fiscal 2003 and \$0.9 million for Fiscal 2002. 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.

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We expect approximately \$2.0 million in capital expenditures for 2004, principally related to the purchase of laboratory equipment and leasehold improvements.

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	—
<b>Total contractual cash obligations(2)</b>	<b>\$ 1,564,193</b>	<b>\$ 739,517</b>	<b>\$ 594,203</b>	<b>\$ 230,473</b>	<b>\$ —</b>

(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.

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 \$      to \$      to develop M-Dalteparin through the filing of an ANDA; and

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- the development of improved product candidates, including using approximately \$      to \$      to develop M118 through Phase I and Phase II clinical trials and \$      to \$      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; and
- the cost of manufacturing, marketing and sales activities, if any;
- 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

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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.

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#### 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.

As disclosed more fully in Note 10 to our financial statements, in lieu of cash payments we granted options to purchase the following number of shares of common stock to non-employees during Fiscal 2003 and 2002:

	Exercise Price Per Share	Number of Shares
2003	\$ 0.29-0.295	95,938
2002	0.29	95,000

We recorded these grants at fair value when granted and re-measure the unvested portion of these grants at each reporting period because these awards either vest over time or upon reaching certain performance objectives.

As disclosed more fully in Note 10 to our financial statements, we granted options to purchase the following number of shares of common stock to employees during Fiscal 2003, 2002 and 2001:

	Exercise Price Per Share	Number of Shares
2003	\$ 0.29-0.77	389,340
2002	0.29	271,202
2001	0.10	14,933

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 December 31, 2003, 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.

### 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 detectable 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.

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, 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 approximately six to 12 months after our M-Enoxaparin submission. 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 significant potential benefits of M118 over UFH and other LMWHs, though results from animal tests are not always duplicated when product candidates are tested in humans. 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.
- *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.
- *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. 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 quarter 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.

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, which is used to treat multiple sclerosis, also known as Avonex® and Rebif®, and erythropoietin, which is used to treat anemia, also known as Epogen® and Procrit®. 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 significant 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.

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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.

*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

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as a whole, to us than the terms last offered to Sandoz. If we do not enter into a transaction with a third party in the specified time frame, then Sandoz may again exercise the right of first negotiation with respect to these opportunities.

Under this collaboration, Sandoz will make certain payments to us. We will provide, and Sandoz will pay us for, a minimum amount of full-time equivalent scientific, technical and/or management work over the course of the 24-month period that commenced on October 1, 2003. Sandoz

is also responsible for funding substantially all of the other ongoing development and commercialization costs and legal expenses incurred with respect to injectable enoxaparin, subject to an agreed-upon limit. To date, Sandoz has paid us approximately \$2.0 million for our work and the reimbursement of development costs. In addition, Sandoz will share profits with us or pay royalties to us on net sales of injectable enoxaparin by Sandoz, its affiliates or distributors in the United States. If certain regulatory or commercial milestones are achieved with respect to injectable enoxaparin under certain circumstances, Sandoz may also make certain milestone payments to us, which would reach \$55.0 million if all such milestones are achieved. If the development expenses and certain legal expenses, in the aggregate, exceed a specified amount, Sandoz is permitted to offset a portion of the excess against the profit-sharing amounts, the royalties and the commercial milestone payments. Sandoz may also offset a portion of any product liability costs and certain other expenses arising from patent litigation against the profit-sharing amounts, the royalties and the commercial milestone payments.

The collaboration is governed by a joint steering committee and a joint project team, each consisting of an equal number of Sandoz and Momenta representatives. Most decisions must be made unanimously, with Sandoz collectively having one vote and us having one vote. Sandoz has sole authority to make decisions with respect to any litigation claiming that the manufacture, use or sale of the injectable enoxaparin product infringes any patents listed in the Orange Book for Lovenox. In addition, Sandoz has the sole authority to determine whether or not to launch the injectable enoxaparin product prior to receipt of final legal clearance from any such infringement claims, as well as the price at which it will sell the injectable enoxaparin product. Sandoz is also responsible for the filing of the ANDA.

We and Sandoz will indemnify each other for losses resulting from the indemnifying party's misrepresentation or breach of its obligations under the agreement. We will indemnify Sandoz if we actually misappropriate the know-how or trade secrets of a third party. Sandoz will indemnify us and our collaborators involved in the enoxaparin program for any losses resulting from any litigation by third parties, including Aventis, claiming that the manufacture, use or sale of injectable enoxaparin infringes any patents listed in the Orange Book for Lovenox, any product liability claims with respect to injectable enoxaparin and any other claims relating to the development and commercialization of injectable enoxaparin. To the extent that any losses result from a third party claim for which we are obligated to indemnify Sandoz, Sandoz will have no obligation to indemnify us. After the expiration or termination of the agreement, these indemnification obligations will continue with respect to claims that arise before or after the termination of the agreement due to activities that occurred before or during the term of the agreement.

Unless terminated earlier, the agreement will expire upon the last sale of injectable enoxaparin by or on behalf of Sandoz in the United States. Either party may terminate the collaboration relationship for material uncured breaches or certain events of bankruptcy or insolvency by the other. Sandoz may also terminate the agreement if the product or the market lacks commercial viability, if 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 (except due to our uncured breach) or if we terminate the agreement due to an uncured breach by Sandoz, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize injectable enoxaparin in the United States and our obligation to indemnify Sandoz will survive with respect to

claims that arise due to our exclusive development or commercialization of injectable enoxaparin after the term of the agreement. In the event of a termination by Sandoz due to the incurrence of costs beyond the agreed upon limits, we must pay certain royalties to Sandoz on our net sales of injectable enoxaparin. If Sandoz terminates the agreement due to our uncured breach, Sandoz retains the exclusive right to develop and commercialize injectable enoxaparin in the United States, and, if the negotiation period with respect to a license outside of the United States is not yet complete, Sandoz shall continue to have the right to negotiate an exclusive license. In addition, Sandoz' profit sharing, royalty and milestone payment obligations survive and Sandoz' obligation to indemnify us will survive with respect to claims that arise due to Sandoz' exclusive development or commercialization of injectable enoxaparin after the term of the agreement. In addition, if Sandoz terminates the agreement due to our uncured breach, Sandoz would retain its rights of first negotiation with respect to certain of our other products.

### ***Massachusetts Institute of Technology***

In December 2001, we entered into an exclusive patent license agreement with the Massachusetts Institute of Technology, or M.I.T., that was subsequently amended and restated in early November 2002 and further amended in 2003. We entered into an additional exclusive patent license agreement with M.I.T. in late October 2002. These two agreements grant us various exclusive and nonexclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to methods and technologies for analyzing and characterizing sugars, certain heparins, heparinases and other enzymes, synthesis methods and automated sequencing. Subject to typical retained rights of M.I.T. and the United States government, we are granted exclusive rights under certain of these patents and patent applications in certain fields. Under certain circumstances, we must meet certain diligence requirements in order to maintain our licenses under the two agreements. Under the amended and restated license agreement, M.I.T. may convert our exclusive licenses to non-exclusive licenses, as its sole remedy, if we fail to fulfill our diligence obligations. Under the October 2002 license agreement, we may under certain circumstances be required to meet certain diligence requirements in order to maintain our license, and M.I.T. has the right to treat our failure to fulfill our diligence obligations as a material breach of the agreement.

We have a first option to expand our exclusive licenses by adding rights to those patentable inventions which are made by certain M.I.T. investigators by December 31, 2004 and which are dominated by claims of certain of the patents or applications under which we are exclusively licensed, provided that we pay a fee to M.I.T.

In exchange for the licenses granted in the two agreements, we paid M.I.T. license issue fees and we pay annual license maintenance fees. In addition, in exchange for the licenses granted under the amended and restated license agreement, M.I.T. was issued 229,013 shares of our common stock valued at \$0.3 million and certain employees of M.I.T. who are inventors of the licensed patents and patent applications were issued an aggregate of 63,953 shares of our common stock valued at \$0.1 million. We are also required to pay M.I.T. royalties on products and services covered by the licenses and sold by us or our affiliates or sublicensees, a percentage of certain other income received by us from corporate partners and sublicensees, and certain patent prosecution and maintenance costs.

We are obligated to indemnify M.I.T. and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements, unless the losses result from the indemnified parties' gross negligence or willful misconduct.

Each agreement expires upon the expiration or abandonment of all issued patents and filed patent applications licensed to us by M.I.T. under such agreement. The issued patents include 10 United States patents that expire between 2012 and 2022, and a number of foreign patents that expire between 2012 and 2013. We expect that additional patents will issue from filed patent applications. Any such patent

will have a term of 20 years from the filing date of the underlying application. M.I.T. may terminate either or both agreements immediately if we cease to carry on our business, if any nonpayment by us is not cured within 60 days of written notice or if we commit a material breach that is not cured within 90 days of written notice. We may terminate either or both agreements for any reason upon six months notice to M.I.T., and, under one agreement, we can separately terminate the license under a certain subset of patent rights upon three months notice.

We have granted Sandoz a sublicense under the amended and restated license agreement to certain of the patents and patent applications licensed to us. If M.I.T. converts our exclusive licenses under this agreement to non-exclusive due to our failure to meet diligence obligations, or if M.I.T. terminates this agreement, M.I.T. will honor the exclusive nature of the sublicense we granted to Sandoz so long as Sandoz continues to fulfill its obligations to us under the collaboration and license agreement we entered into with Sandoz and, if our agreement with M.I.T. is terminated, Sandoz agrees to assume our rights and obligations to M.I.T.

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

In November 2002, we entered into an agreement with The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory, or Lawrence Berkeley National Lab, under which we exclusively licensed certain patents and patent applications covering the metabolic synthesis of sugars and glycoconjugates. Subject to typical retained rights of Lawrence Berkeley National Lab and the United States government, we were initially granted an exclusive license, with the right to grant sublicenses, for the synthesis, production or modification of sugars and glycoconjugates in or on biological molecules for purposes of researching, developing and commercializing products, services and processes for all human therapeutic applications, excluding the sale of research reagents. After November 20, 2004, we may retain the license under this broad field if we have met certain diligence obligations and pay a fee. If we do not do so, the field narrows to three therapeutic applications that we select from an agreed upon list, each to be more thoroughly defined through negotiation with Lawrence Berkeley National Lab. Upon our request, but subject to statutory restrictions or obligations to research sponsors, Lawrence Berkeley National Lab must disclose certain information that is necessary or useful for our use of the licensed patent rights and we have a non-exclusive, royalty-free right to use such information.

Lawrence Berkeley National Lab has an obligation to notify us of certain future inventions that are available for licensing by Lawrence Berkeley National Lab prior to entering into negotiations with others. However, Lawrence Berkeley National Lab is not required to license those inventions to us, or even to negotiate with us.

In return for these license rights, we paid Lawrence Berkeley National Lab a license issue fee. We are also required to pay Lawrence Berkeley National Lab earned royalties on products, services and processes covered by the license and sold by us or our affiliates or sublicensees, a percentage of certain other income received by us from our sublicensees, and patent prosecution and maintenance costs. To the extent that earned royalties in any given year do not meet certain threshold amounts, we are required to make annual minimum royalty payments to Lawrence Berkeley National Lab in order to maintain the license.

We must also meet on-going diligence milestones. If we fail to do so, Lawrence Berkeley National Lab may renegotiate the milestones, terminate the agreement or convert the exclusive license to a non-exclusive license.

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

The agreement expires upon the later of the expiration, abandonment or final adjudication of invalidity of the licensed patents. The licensed patents consist of two United States patents that expire in 2017 and 2020 and one United States patent application. Any patent issuing from such application will have a term of 20 years from the date such application was filed. Our license to use the know-how acquired from Lawrence Berkeley National Lab is paid-up and perpetual following the expiration, but not an earlier termination, of the agreement. Either party may terminate the agreement for the other's material breach with a 90 day cure period, although Lawrence Berkeley National Lab may terminate if we do not cure payment breaches within 30 days. We may terminate the agreement for any reason upon 180 days notice. Upon termination of the agreement, we are required to assign each sublicense to Lawrence Berkeley National Lab and Lawrence Berkeley National Lab is required to assume it unless the sublicensee is then in breach or the sublicense conflicts with Lawrence Berkeley National Lab's obligations to state or federal governments.

#### **Manufacturing**

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

In each of our agreements with contract manufacturers, we retain ownership of our intellectual property and generally own and/or are assigned ownership of processes, developments, data, results and other intellectual property generated during the course of the performance of each agreement that primarily relate to our products. Where applicable, we are granted non-exclusive licenses to certain contract manufacturer intellectual property for purposes of exploiting the products that are the subject of the agreement and in a few instances we grant non-exclusive licenses to the contract manufacturers for use outside of our product area. In each contract, we have the right to terminate for convenience. The agreements also contain typical provisions for both parties to terminate for material breach and bankruptcy and insolvency.

#### ***M-Enoxaparin***

In October 2003, we entered into a process development and production agreement with Siegfried (USA), Inc. and Siegfried Ltd. under which

we provide to Siegfried our existing laboratory-scale processes and analytical methods for the production of M-Enoxaparin. Siegfried's responsibility is to further develop the processes and once we approve of such processes, manufacture the active pharmaceutical ingredient, enoxaparin sodium, for use in stability, preclinical and clinical studies and for other development purposes. During the term of the agreement and for a period of time thereafter, Siegfried commits to work with us on the development and production of M-Enoxaparin on an exclusive basis.

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

Siegfried is obligated to indemnify us for third-party product liability claims which result from the failure of the product to meet certain requirements and/or the negligence or misconduct of Siegfried.

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

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

We are working with a provider for analytical testing, method transfer, validation and preparation work and for comparability studies for M-Enoxaparin and are negotiating with a contract manufacturer to produce M-Enoxaparin in finished dose form for development and clinical use.

#### ***M-Dalteparin***

Should we require process development of M-Dalteparin, we expect the manufacture of M-Dalteparin would require similar process development as M-Enoxaparin; however, we may or may not use the same contract manufacturers selected for M-Enoxaparin.

#### ***M118***

We are working with a provider to perform process development and enzyme production work for a specific heparinase enzyme which is used to produce M118. In addition, we are working with a contract manufacturer with regard to our existing laboratory-scale processes and analytical methods for the production of M118, including the heparinase enzyme used to produce M118.

### **Sales and Marketing**

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

### **Competition**

The development and commercialization of pharmaceutical products is highly competitive. In the event that we were to market and sell M-Enoxaparin, we would face competition from Aventis which is currently marketing Lovenox, and potentially from other firms marketing generic versions of Lovenox. Aventis may also choose to market a generic version of Lovenox itself or through an authorized third-party distributor. While there are no generic versions of Lovenox approved by the FDA to date,

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ANDAs have been submitted to the FDA by Amphastar and Teva, and other ANDAs or other regulatory applications may be submitted in the future. Any generic enoxaparin application must demonstrate that its product has the same active ingredients as Lovenox, in accordance with the FDA's requirement for therapeutic equivalence and to be considered interchangeable with Lovenox. We believe that other firms submitting ANDAs will face difficulty in demonstrating that they have the same active ingredients as Lovenox, given the difficulties associated with the detailed analysis of Lovenox. M-Dalteparin will face similar competition from Pfizer, which is currently marketing Fragmin, and other manufacturers seeking to commercialize generic versions of Fragmin in the United States.

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

- Sanofi-Synthelabo's factor Xa inhibitor, Arixtra®, which has multiple indications in DVT;

- The Medicines Company's direct thrombin inhibitor, Angiomax®, which is approved for use in angioplasty; and
- various UFH products.

We are aware of other anticoagulant drugs in development, including AstraZeneca's Exanta®, which is currently in Phase III clinical trials, as well as multiple factor Xa inhibitors in clinical trials.

M118 faces competition from similar compounds, including other LMWHs, UFH, as well as anti-platelet and direct thrombin inhibitors which may be used in the treatment of ACS. As the treatment for ACS evolves, other classes of products may become increasingly more important in the treatment of ACS; however, we believe that LMWH therapy will remain a critical element of ACS treatment. AstraZeneca and Sanofi-Synthelabo have publicly disclosed they will seek approval for selected ACS indications for Exanta and Arixtra, respectively.

In the areas of non-invasive drug delivery, there are many companies seeking to advance pulmonary delivery for therapeutic proteins. Current companies active in the drug delivery field include Alkermes Inc., Aradigm Corporation, Aventis, Eli Lilly and Co., Nektar Therapeutics, Novo Nordisk A/S and Pfizer. In addition, there are many major pharmaceutical firms who may pursue non-invasive delivery as line extension strategies for existing products. These companies could become competitors or collaborators for our inhaled product portfolio.

Similarly, our discovery work in oncology faces substantial competition from major pharmaceutical and other biotechnology companies that are actively working on improved and novel therapeutics. Companies competing most directly with our approach of developing sugar-based therapeutics for oncology include GlycoGenesys Inc. and Progene.

The key competitive factors affecting the overall success of our prospective drug products include: product effectiveness, safety, timing and scope of regulatory approval, price, availability of supply/manufacturing efficiency, and patent protection.

Companies may also emerge as competitors over time, as their technology and products may reduce market demand for our technology and/or products. Examples of potential future competitors include companies working on:

- Novel drug products in our target therapeutic areas, such as new cardiovascular therapies that significantly alter the market potential for existing drug products to which we may apply our technology;
- Novel drug products possessing superior clinical attributes to our development candidates;

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- Alternative delivery mechanisms for drug products in our target therapeutic areas which may decrease the attractiveness of our molecules, such as oral heparin products which may reduce the demand for subcutaneous drug products, even those with improved product profiles; and
- Second-generation versions of drugs which are subject to research and development efforts within pharmaceutical companies that may alter the demand for selected products.

The field of glycobiology is a growing field with increased competition. While we are not aware of others that are taking a similar approach to detailed chemical characterization of complex sugars, there are companies that could be viewed as competitors in the broader context of glycobiology. In addition to major pharmaceutical and biotechnology companies which have successfully improved products through sugar modification, such as Amgen and Biogen Idec Inc., there are many companies with glycobiology capabilities, including BioTie Therapies Oyj, GLYCO Design Inc., GlycoFi, Inc., Neose Technologies, Inc., Procognia Limited and Pro-Pharmaceuticals Inc. Competitive factors distinguishing companies include the breadth and comprehensiveness of their analytic capabilities, the strength of their patent estates, as well as their relative emphasis on analysis, synthesis, or engineering of complex sugars. Many of these companies are focused on providing services to pharmaceutical companies rather than focused on drug discovery and product development.

### Patents and Proprietary Rights

Our success depends in part on our ability to obtain and maintain proprietary protection for our technology and product candidates, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications related to our proprietary technology and product candidates that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We license or own a total of 12 United States patents and 24 United States patent applications as well as 17 foreign patents and 48 foreign patent applications which are counterparts to certain of the United States patents and patent applications. Our patent portfolio includes claims covering: methods and technologies for characterizing sugars; the composition of matter of certain naturally occurring heparinases, heparinase variants and other enzymes which specifically recognize polysaccharides and the use of these heparinases and enzymes in the characterization of sugars; methods and technologies for chemical and metabolic synthesis of sugars; the composition of matter of certain novel low molecular weight heparins, including M118; methods to produce and identify sugars associated with glycoproteins; methods to analyze and monitor glycoprotein profiles for purposes associated with the diagnosis, staging, prognosis and monitoring of cancer; and methods for the *in vivo* non-invasive delivery of sugars.

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The following is a table that sets forth the 12 United States patents we license:

U.S. Number	Filing Date/ Issue Date	Expiration Date	Licensor	Title
5,714,376	10/23/91 02/03/98	02/03/2015	M.I.T.	Heparinase Gene From Flavobacterium Heparinum
5,830,726	05/19/95 11/03/98	11/03/2015	M.I.T.	Method for Obtaining A Modified Heparinase Gene
5,389,539	11/30/92 02/14/95	02/14/2012	M.I.T. – University of Iowa Research Foundation	Purification Of Heparinase I, II, and III From Flavobacterium Heparinum
5,569,600	01/26/95 10/29/96	10/29/2013	M.I.T. – University of Iowa Research Foundation	Purification, Composition, and Specificity Of Heparinase I, II, And III From Flavobacterium Heparinum
5,607,859	03/28/94 03/04/97	03/04/2014	M.I.T.	Methods And Products For Mass Spectrometric Molecular Weight Determination Of Polyionic Analytes Employing Polyionic Reagents
6,597,996	04/24/00 07/22/03	04/24/2020	M.I.T.	Method For Identifying Or Characterizing Properties of Polymetric Units
6,323,339	10/06/99 11/27/01	10/06/2019	M.I.T.	Synthesis of Oligosaccharides, Reagents And Methods Related Thereto
6,579,725	03/03/00 06/17/03	03/03/2020	M.I.T.	Linkers for Synthesis of Oligosaccharides On Solid Supports
6,426,421	11/21/00 07/30/02	11/21/2020	M.I.T.	Protecting Groups Useful in the Synthesis Of Polysaccharides, Natural Products, And Combinatorial Libraries
6,693,178	05/15/02 02/17/04	05/15/2022	M.I.T.	Protecting Groups Useful In The Synthesis Of Polysaccharides, Natural Products, And Combinatorial Libraries
6,075,134	05/15/97 06/13/00	05/15/2017	The Regents of the University of California	Glycoconjugates and Methods
6,458,937	05/16/00 10/01/02	05/16/2020	The Regents of the University of California	Glycoconjugates and Methods

A significant portion of our patent portfolio covering methods and technologies for characterizing sugars consists of patents and patent applications owned and licensed to us by M.I.T. In addition, a

significant portion of the claims in our patent portfolio covering the composition of matter of naturally occurring heparinases, heparinase variants and other enzymes, the use of these heparinases and enzymes in the characterization of sugars, the methods and technologies for chemical synthesis of sugars, and the composition of matter of novel low molecular weight heparins consist of patents and patent applications that are owned and licensed to us by M.I.T. The claims in our patent portfolio covering the methods and technologies for metabolic synthesis of sugars consist of patents and patent applications that are owned and licensed to us by Ernest Orlando Lawrence Berkeley National Laboratory.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents. Moreover, any issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of the term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for both our generic and novel products. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible

that, before any of our novel heparin or other products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by confidentiality agreements with our employees, consultants, advisors, contractors and collaborators. These agreements may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, advisors, contractors and collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

## **Regulatory and Legal Matters**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of products such as those we are developing.

### ***United States Government Regulation***

In the United States, the information that must be submitted to the FDA in order to obtain approval to market a new drug varies depending on whether the drug is a new product whose safety and effectiveness has not previously been demonstrated in humans or a drug whose active ingredient(s) and certain other properties are the same as those of a previously approved drug. A new drug will follow the NDA route, a new biologic will follow the BLA route, and a drug that claims to be the same as an already approved drug may be able to follow the ANDA route. Medical devices are approved or cleared for marketing through either the premarket approval application process, or PMA process, or

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the 510(k) clearance process. Drugs or biologics that are combined with medical devices may be regulated as combination products through one or more of the FDA's regulatory pathways.

### ***NDA and BLA Approval Processes***

In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act, and, in the case of biologics, also under the Public Health Service Act, and implementing regulations. Failures to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The steps required before a drug or biologic may be marketed in the United States include:

- completion of preclinical laboratory tests, animal studies and formulation studies under the FDA's current good laboratory practices;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin and must include independent IRB approval at each clinical site before the trial is initiated;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each indication;
- submission to the FDA of a NDA, or BLA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity or to meet standards designed to ensure the biologic's continued safety, purity and potency; and
- FDA review and approval of the NDA or BLA.

Preclinical tests include laboratory evaluations of product chemistry, toxicity, and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. Submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each clinical protocol must be submitted to the FDA as part of the IND, and an IRB at each site where the study is conducted must also approve the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Phase I trials usually involve the initial introduction of the investigational drug into humans to evaluate the product's safety, dosage tolerance and pharmacodynamics and, if possible, to gain an early indication of its effectiveness.

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Phase II trials usually involve controlled trials in a limited patient population to:

- evaluate dosage tolerance and appropriate dosage;
- identify possible adverse effects and safety risks; and
- evaluate the preliminary efficacy of the drug for specific indications.

Phase III trials usually further evaluate clinical efficacy and test further for safety in an expanded patient population. Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. Furthermore, the FDA or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the chemistry, manufacture and control criteria of the product, are submitted to the FDA in the form of an NDA or BLA requesting approval to market the product for one or more indications. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. The FDA reviews a BLA to determine, among other things, whether the product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency.

Before approving an NDA or BLA, the FDA will inspect the facility or the facilities at which the product is manufactured. The FDA will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

#### **ANDA Process**

FDA approval is required before a generic equivalent of an existing brand name drug can be marketed. Such approval for products is typically obtained by submitting an ANDA to the FDA and demonstrating therapeutic equivalence. However, it is within the FDA's regulatory discretion to determine the kind and amount of evidence required to approve a product for marketing. Although the FDA has accepted ANDAs for generic versions of Lovenox for review, the FDA could determine that therapeutic equivalence cannot be shown for M-Enoxaparin and require an NDA for approval. An ANDA may be submitted for a drug on the basis that it is the same as a previously approved branded drug, also known as a listed drug. Specifically, the generic drug that is the subject of the ANDA must have the same active ingredient(s), route of administration, dosage form, and strength, as well as the same labeling, with certain exceptions, and the labeling must prescribe the same conditions of use as the listed drug. If the generic drug product has a different route of administration, dosage form, or strength, the FDA must grant a suitability petition approving the differences(s) from the listed drug before the ANDA may be filed. The ANDA must also contain data and information demonstrating that

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the generic drug is bioequivalent to the listed drug, or if the application is submitted pursuant to an approved suitability petition, information to show that the active ingredients in the generic drug are the same pharmacological or therapeutic class as those of the listed drug and that the generic drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a proposed condition of use.

Generic drug applications are termed "abbreviated" because they are not required to duplicate the clinical (human) testing or, generally, preclinical testing necessary to establish the underlying safety and effectiveness of the branded product. However, the FDA may refuse to approve an ANDA if there is insufficient information to show that the active ingredients are the same and to demonstrate that any impurities or differences in active ingredients do not affect the safety or efficacy of the generic product. In addition, like NDAs, an ANDA will not be approved unless the product is manufactured in cGMP-compliant facilities to assure and preserve the drug's identity, strength, quality and purity. Moreover, submission of an ANDA does not guarantee it will be deemed acceptable for filing and review; the FDA may refuse to accept for filing applications it finds insufficiently complete.

Determination of the "sameness" of the active ingredients to that in the listed drug is based on the demonstration of the chemical equivalence of the components of the generic version to those of the branded product. The FDA defines active ingredients as "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. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." While the standard of demonstrating chemical equivalence is relatively straightforward for small molecule drugs, it is inherently more difficult to define active ingredients for complex drugs, including those made from naturally occurring biological substances. These include heparins, therapeutic proteins, vaccines and antibiotics. The FDA has not reached a final position or provided specific guidance for demonstrating chemical equivalence for many of these products as criteria are in many cases, still evolving.

To demonstrate bioequivalence, ANDAs generally must also contain *in vivo* bioavailability data for the generic and branded drugs. "Bioavailability" indicates the rate and extent of absorption and levels of concentration of a drug product in the blood stream needed to produce a therapeutic effect. "Bioequivalence" compares the bioavailability of one drug product with another, and when established, indicates that the rate of absorption and levels of concentration of a generic drug in the body are the same as the previously approved branded drug. If the rate of absorption is different but the extent of absorption is the same, and the difference in rate is intentional and reflected in the proposed labeling, two

drugs may be considered bioequivalent if the difference is not essential to the effective attainment of body drug concentrations on chronic use, and is considered medically insignificant for the drug. The studies required to demonstrate *in vivo* bioequivalence are generally very small, quick to complete, and involve few patients. Under current regulations, for certain drug products where bioequivalence is self-evident such as injectable solutions which have been shown to contain the same active and inactive ingredients as the listed drug, the FDA may waive the requirement for *in vivo* bioequivalence data. Thus, most generic injectable products approved to date have been able to successfully obtain waivers to bioequivalence testing in humans.

Generic drug products that are found to be therapeutically equivalent by the FDA receive an "A" rating in FDA's Orange Book, which lists all approved drug products and therapeutic equivalence evaluations. Products that are therapeutically equivalent can be expected in FDA's judgment to have equivalent clinical effect and no difference in their potential for adverse effects when used under the conditions of their labeling. Products with "A" ratings are generally substitutable for the innovator drug by both in-hospital and retail pharmacies. Many health insurance plans require automatic substitution

for "A" rated generic versions of products when they are available, although physicians may still prescribe the branded drug for individual patients.

The timing of final FDA approval of a generic drug for commercial distribution depends on a variety of factors, including whether the applicant challenges any listed patents for the drug and/or its use and whether the manufacturer of the branded product is entitled to one or more statutory exclusivity periods, during which the FDA is prohibited from approving generic products. In addition, submission of an ANDA for a drug that was a new molecular entity when approved will be blocked for five years after the pioneer's approval, or for four years after approval if the application includes a paragraph IV certification of non-infringement or invalidity against a patent applicable to the branded drug. This does not apply to M-Enoxaparin and M-Dalteparin but may apply to future generic products that we pursue. In certain circumstances, a regulatory exclusivity period can extend beyond the life of a patent, and thus block ANDAs from being approved on or after the patent expiration date. For example, the FDA may now extend the exclusivity of a product by six months past the date of patent expiry if the manufacturer undertakes studies on the effect of their product in children, a so-called pediatric extension. The FDA has requested pediatric studies of Lovenox from Aventis. If Aventis undertakes these studies, Lovenox could be eligible for a six month extension of exclusivity.

### **Combination Product Regulation**

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

### **Approval or Clearance of Medical Devices**

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

### **Post Approval Requirements**

After regulatory approval of a product is obtained, we are required to comply with a number of post-approval requirements. For example, as a condition of approval of an NDA, BLA or PMA the FDA may require post marketing testing and surveillance to monitor the product's safety or efficacy.

In addition, holders of an approved NDA, BLA, PMA or ANDA or cleared 510(k) are required to report certain adverse reactions and production problems to the FDA to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes certain procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We use, and will continue to use in at least the near term, third party manufacturers to produce our products in clinical and commercial quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, BLA, PMA, or ANDA or cleared 510(k), including withdrawal or recall of the product from the market or other voluntary FDA-initiated or judicial action that could delay or

prohibit future marketing. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

### ***Patent Challenge Process Regarding ANDAs***

The Hatch-Waxman Act provides incentives for generic pharmaceutical manufacturers to challenge patents on branded pharmaceutical products and/or their methods of use, as well as to develop products comprising non-infringing forms of the patented drugs. The Hatch-Waxman legislation places significant burdens on the ANDA filer to ensure that such challenges are not frivolous, but also offers the opportunity for significant financial reward if the challenge is successful.

If there is a patent listed for the branded drug in FDA's Orange Book at the time of submission of the ANDA or at any time before the ANDA is approved and the generic company intends to market the generic equivalent prior to the expiration of that patent, the generic company includes a certification asserting that the patent is invalid, unenforceable and/or not infringed, a so-called "paragraph IV certification."

After receiving notice from the FDA that its application is acceptable for review or immediately if the ANDA has been amended to include a paragraph IV certification after the application was submitted to the FDA, the company filing a generic application is required to send the patent holder and the holder of the NDA for the brand-name drug a notice explaining why it believes that the patents in question are invalid, unenforceable or not infringed. Upon receipt of the notice from the generic applicant, the patent holder has 45 days during which to bring a patent infringement suit in federal district court against the generic applicant in order to obtain the 30 month automatic stay.

If a suit is commenced by the patent holder during the 45 day period, the Hatch-Waxman Act provides for an automatic stay on the FDA's ability to grant final approval of the ANDA for the generic product. Patent holders may only obtain one 30 month stay with respect to patents that were listed at the time an ANDA was filed. The period during which the FDA may not approve the ANDA and the patent challenger therefore may not market the generic product is 30 months, or such other period as may be ordered by the court. The 30-month period may or may not, and often does not, coincide with the timing of the resolution of the lawsuit or the expiration of a patent, but if the patent

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challenge is successful or the challenged patent expires during the 30-month period, the FDA may approve the generic drug for marketing, assuming there are no other obstacles to approval such as periods of non-patent exclusivity given to the NDA holder.

Under the Hatch-Waxman Act, any developer of a generic drug that is considered first to have its ANDA accepted for review by the FDA, and whose filing includes a paragraph IV certification, may be eligible to receive a 180-day period of generic market exclusivity. This period of market exclusivity may provide the patent challenger with the opportunity to earn a return on the risks taken and its legal and development costs and to build its market share before other generic competitors can enter the market. If the ANDA of the first applicant accepted for filing is withdrawn, the 180-day exclusivity period is forfeited and unavailable to any other applicant. The Medicare Prescription Drug Improvement and Modernization Act of 2003 provides for the elimination of the 180 day exclusivity period if, among other reasons, the company that is first to submit an ANDA does not receive tentative approval from the FDA within 30 months after acceptance for filing of the ANDA submission. However, neither Teva nor Amphastar will be subject to that forfeiture provision because it is not retroactive.

### ***Foreign Regulation***

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

Under European Union regulatory systems, we may submit marketing authorizations either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

### ***Related Matters***

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

### ***Lovenox Regulatory and Legal Matters***

On February 19, 2003, a Citizen Petition was submitted to FDA on behalf of Aventis to request that the FDA withhold approval of any ANDA for a generic version of Lovenox until the conditions set forth in the 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 enoxaparin or the application is supported by proof of equivalent safety and effectiveness demonstrated through clinical trials. To date, however, the FDA has not publicly responded to Aventis' Citizen Petition.

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Companies that produce branded pharmaceutical products routinely bring litigation against generic applicants seeking FDA approval to

manufacture and market generic forms of their branded products prior to the expiry of patents listed in the Orange Book. These companies typically allege patent infringement as the basis for filing suit against a generic applicant.

On May 7, 2003, Aventis filed a re-issue application for the '618 patent in the United States Patent and Trademark Office. The inventor declared the original patent to be partly inoperative by reason of a defective specification. The patent will remain in force as a granted patent during the reissue proceeding. Aventis has stated that if the application is approved, Aventis believes that the '618 patent could be re-issued prior to year end 2004.

In June 2003, Aventis announced that it received notices from Amphastar and independently from Teva that ANDAs had been filed by each company with the FDA with a paragraph IV certification against the '618 patent seeking authorization to produce and market a generic version of Lovenox in the United States.

In August 2003, Aventis sued Amphastar and Teva in two different United States District Courts: New Jersey and in the Central District of California. Amphastar and Teva assert non-infringement and invalidity of the '618 patent and have also sought related declaratory judgment relief. In February 2004, the New Jersey case was ordered to be transferred to the Central District of California, where the court has set a discovery schedule and a trial date of April 2005.

A November 2003 preliminary amendment by Aventis shows that the specification of the '618 patent was amended and that one claim was cancelled. In the Preliminary Amendment, Aventis maintained the validity of the remaining claims of the '618 patent over, among other things, the arguments raised in the notice letters provided by Amphastar and Teva.

We intend to explore all available legal and regulatory options to gain approval for and market our generic enoxaparin product prior to expiration of the '618 patent. If and when we attempt to commercialize M-Enoxaparin, we expect to face significant litigation from Aventis.

Depending upon a thorough analysis of a variety of legal and commercial factors, our collaborator, Sandoz, may, in certain circumstances, upon expiration of the 30-month automatic stay on the FDA's ability to grant approval of an ANDA, elect to market M-Enoxaparin, if approved, even though litigation is still pending. This could be before any court decision is rendered or while an appeal of a lower court decision is pending. Should we elect to proceed in this manner, we could face substantial patent liability damages if the final court decision is adverse to us. With certain exceptions, Sandoz will indemnify us for any losses we may incur or must pay to a third party which may result from patent infringement litigation by Aventis and certain other claims. Litigation often involves significant expense or may delay or prevent introduction of M-Enoxaparin. If we are not successful in commercializing M-Enoxaparin, or if we are significantly delayed in doing so, our business will be materially harmed.

#### **Hazardous Materials**

Our research and development processes involve the controlled use of hazardous materials and chemicals, including sodium azide, cetylpyridinium chloride monohydrate, 4-chlorobenzyl chloride, sodium nitrite pyridine, sodium cyanoborohydride and barium acetate. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material.

#### **Employees**

We believe that our success will depend greatly on our ability to identify, attract and retain capable employees. As of March 1, 2004, we had 33 employees, including a total of 13 employees who hold

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M.D. or Ph.D. degrees. Our employees are not represented by any collective bargaining unit, and we believe our relations with our employees are good.

#### **Facilities**

As of December 31, 2003, we leased a total of approximately 13,900 square feet of office and laboratory space. Our leased properties are described below:

<u>Property Location</u>	<u>Approximate Square Footage</u>	<u>Use</u>	<u>Lease Expiration Date</u>
43 Moulton Street Cambridge, Massachusetts 02138	5,300	Laboratory & Office	08/31/2004
68 Moulton Street Cambridge, Massachusetts 02138	8,600	Office	08/31/2004

We have signed a non-binding letter of intent with a third party to enter into a ten year lease for approximately 24,000 square feet of office and laboratory space in Cambridge, Massachusetts, scheduled to commence on September 1, 2004.

#### **Legal Proceedings**

We are currently not a party to any material legal proceedings.

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## **MANAGEMENT**

Our executive officers, directors and other significant employee, and their ages and positions as of March 1, 2004, are set forth below:

Name	Age	Position
<b>Executive Officers and Directors</b>		
Alan L. Crane	40	Chairman of the Board, President and Chief Executive Officer
Steven B. Brugger	45	Vice President, Strategic Product Development
Richard P. Shea	52	Vice President and Chief Financial Officer
Joseph E. Tyler	53	Vice President, Manufacturing
Ganesh Venkataraman, Ph.D.	37	Co-Founder and Vice President, Technology
Susan K. Whoriskey, Ph.D.	45	Vice President, Licensing and Business Development
Peter Barrett, Ph.D.(2)(3)	50	Director
John K. Clarke(1)	50	Director
Peter Barton Hutt, LL.B., LL.M.(2)	69	Director
Robert S. Langer, Jr., Sc.D.	55	Co-Founder and Director
Stephen T. Reeders, D.M., MRCP(1)	50	Director
Ram Sasisekharan, Ph.D.	39	Co-Founder and Director
Bennett M. Shapiro, M.D.(3)	64	Director
Christoph H. Westphal, M.D., Ph.D.(2)(3)	35	Co-Founder and Director
John L. Zabriskie, Ph.D.(1)	64	Director
<b>Significant Employee</b>		
Ian D. Fier	37	Senior Director, Development Operations

- (1) Member of Audit Committee
- (2) Member of Nominating and Corporate Governance Committee
- (3) Member of Compensation Committee

*Alan L. Crane* has been a director since June 2001 and our Chairman of the Board, President and Chief Executive Officer on a full-time basis since May 2002. From February 1997 to May 2002, Mr. Crane held various management positions at Millennium Pharmaceuticals, Inc., a biopharmaceutical company. He most recently served as Senior Vice President, Global Corporate Development, where he led Millennium's strategic alliance, mergers and acquisitions and licensing activities. Mr. Crane serves on the boards of the following privately held companies: Compound Therapeutics, Inc., Vaccinex, Inc. and Control Delivery Systems, Inc. Mr. Crane serves as a venture partner at Polaris Venture Partners, a venture capital firm, and as a Member of the Board of Overseers of Children's Hospital Boston, a not for profit teaching affiliate of Harvard Medical School. Mr. Crane received his B.A. in Biology, *summa cum laude*, from Harvard College and both his M.A. in Biology and M.B.A. in General Management from Harvard University.

*Steven B. Brugger* has been our Vice President, Strategic Product Development since August 2002. From October 1999 to August 2002, Mr. Brugger served as a Vice President for Millennium Pharmaceuticals, Inc., a biopharmaceutical company, where he built Millennium's strategic marketing, project management and portfolio management capabilities. During his tenure at Millennium, Mr. Brugger served as Head of Commercial Development, General Manager of the Inflammation and Metabolic Business Units, and Development Projects Leader for the Aventis and Abbott collaborations. From 1984 to October 1999, Mr. Brugger worked at Novartis Pharmaceuticals, a pharmaceutical company, most recently serving as Executive Director of Marketing for the Transplant, Tissue

Engineering, and Immunology Business Unit. Mr. Brugger received his B.A. in Biology from Susquehanna University and his M.B.A. from Rutgers University.

*Richard P. Shea* has been our Vice President and Chief Financial Officer since October 2003. From April 2002 to April 2003, Mr. Shea served as Chief Operating Officer for Variagenics, Inc., a pharmacogenomics company. From March 2000 to April 2002, Mr. Shea served as Variagenics' Chief Financial Officer, and from February 1999 to March 2000, he served as its Vice President, Finance and Administration. While at Variagenics, Mr. Shea was responsible for finance, legal, investor relations, human resources and operations. From April 1997 to January 1999, Mr. Shea was at Genetics Institute, where he served as Vice President of Finance, and from October 1992 to April 1997 he served as its Controller. Mr. Shea is a CPA and received his A.B. from Princeton University and his M.B.A. with High Honors from Boston University.

*Joseph E. Tyler* has been our Vice President, Manufacturing since November 2002. From April 2001 to November 2002, Mr. Tyler served as Vice President of Operations for Salix Pharmaceuticals, Inc., a pharmaceutical company, where he led activities for commercial operations and new product manufacturing development. From April 1995 to March 2001, Mr. Tyler served as Vice President of Manufacturing at GelTex Pharmaceuticals, Inc., a pharmaceutical company, where he managed contract manufacturing from bulk supply to drug product for four novel synthetic polymeric oral drugs. Mr. Tyler received his B.S. in Chemical Engineering from Carnegie Mellon University and his M.S. in Biochemical Engineering from Cornell University.

*Ganesh Venkataraman, Ph.D.* is a co-founder of our company and has been our Vice President, Technology since January 2002. From August 2000 to January 2003, Dr. Venkataraman served as the Director of Bioinformatics for the Consortium for Functional Glycomics, a multi-million dollar NIH initiative to study the role of complex sugars in biology. From March 1995 to July 2000, Dr. Venkataraman was a research faculty member at the Harvard-M.I.T. division of Health and Sciences and Technology, where he investigated the biochemistry and biophysics of carbohydrates and research in the area of analytical techniques for complex carbohydrates. Dr. Venkataraman received his M.S. and Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology.

*Susan K. Whoriskey, Ph.D.* has been our Vice President, Licensing and Business Development since January 2002. From September 2001 to January 2002, Dr. Whoriskey was a biotechnology consultant to Polaris Venture Partners, a venture capital firm, where she implemented the

business operations of Momenta upon the receipt of seed funding and assisted in recruiting team members. From September 1993 to May 2001, Dr. Whoriskey held various management positions at Cubist Pharmaceuticals, Inc., a biopharmaceutical company. Most recently she served as Senior Director of Licensing. As a founding employee she helped recruit management team members, was involved in multiple fundraising rounds, including taking the company public in 1996, and was involved in negotiating numerous pharmaceutical collaborations. Dr. Whoriskey received her B.S. in Microbiology from the University of Massachusetts and her Ph.D. in Molecular Biology from the University of California, Los Angeles. Dr. Whoriskey did a post-doctoral fellowship with a Chemistry emphasis at Harvard University.

*Peter Barrett, Ph.D.* has been a director since May 2003. Dr. Barrett has served as a Senior Partner of Atlas Venture, a venture capital firm, since January 2002. From August 1998 to December 2001, he served as Executive Vice President and Chief Business Officer of Celera Genomics, a biopharmaceutical company, which he co-founded. He also served as Vice President of Celera from 1994 to 1998. Dr. Barrett received his B.S. in Chemistry from Lowell Technological Institute (now known as the University of Massachusetts, Lowell) and his Ph.D. in Analytical Chemistry from Northeastern University. He also completed Harvard Business School's Management Development Program.

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*John K. Clarke* has been a director since April 2002. Mr. Clarke founded Cardinal Partners, a venture capital firm, in 1997 and has served as the Managing General Partner since 1997. He has founded and served as interim Chief Executive Officer of a number of portfolio companies, including Alkermes, Inc., Arris Pharmaceuticals, Inc., the DNX Corporation and Cubist Pharmaceuticals, Inc. Mr. Clarke is a member of the board of directors of Cubist Pharmaceuticals, Inc. He received his B.A. in Biology and Economics from Harvard College and his M.B.A. from the Wharton School of the University of Pennsylvania.

*Peter Barton Hutt, LL.B., LL.M.* has been a director since June 2001. Mr. Hutt has been a partner at the law firm of Covington & Burling and has been an attorney at the firm since 1975. He served as former Chief Counsel for the Food and Drug Administration from 1971 to 1975. Mr. Hutt is a member of the Institute of Medicine of the National Academy of Sciences and teaches a course on Food and Drug Law each Winter Term at Harvard Law School. He has co-authored the casebook used to teach Food and Drug Law and has published numerous papers on food and drug law and health policy. Mr. Hutt is a member of the board of directors of CV Therapeutics, Inc. and several private life sciences companies. Mr. Hutt received his B.A., *magna cum laude*, from Yale University, his LL.B. from Harvard University and his LL.M. from New York University.

*Robert S. Langer, Jr., Sc.D.* is a co-founder of our company and has been a director since May 2001. Dr. Langer is the Kenneth J. Germeshausen Professor of Chemical and Biomedical Engineering at the Massachusetts Institute of Technology and has been on the faculty of M.I.T. since 1977. Dr. Langer is the former Chairman of the Food and Drug Administration Science Board, the FDA's highest advisory board. He has written 780 articles, 450 abstracts and has over 500 issued or pending patents. Dr. Langer has received over 100 major awards, including the 2002 Charles Stark Draper Prize, considered the world's most prestigious engineering prize and the engineering-equivalent of the Nobel Prize. Dr. Langer is a member of the board of directors of Wyeth, Sontra Medical Corporation and Boston Life Sciences, Inc. Dr. Langer received his B.S. from Cornell University and his Sc.D. from the Massachusetts Institute of Technology, both in Chemical Engineering.

*Stephen T. Reeders, D.M., MRCP* has been a director since May 2003. Dr. Reeders is founder and Chief Executive Officer of MVM Limited, a venture capital firm. He has served as the Chief Executive Officer of MVM Limited since June 1997. In this role, he has co-founded three biotechnology companies and is a member of the board of directors of Nova Science Limited, Vasca Inc. and Oxxon Pharmaceuticals, Inc. Prior to founding MVM, Dr. Reeders led healthcare investing at Saunders, Karp & Megrue, a venture capital firm, and served on the faculty of Yale University.

*Ram Sasisekharan, Ph.D.* is a co-founder of our company and has been a director since May 2001. Dr. Sasisekharan has been a Professor of Biological Engineering at the Massachusetts Institute of Technology since 1996. Dr. Sasisekharan's research on complex polysaccharides has led to over 90 publications and over 30 patents, including the core technologies of Momenta. He has won both the Burroughs Wellcome and Beckman Foundation Young Investigator Awards and was the recipient of 1998, 1999, 2000 and 2001 CaPCure Awards from the CaPCure Foundation. Dr. Sasisekharan serves on the steering committee of the Consortium for Functional Glycomics. Dr. Sasisekharan received his Ph.D. in Medical Sciences from Harvard Medical School.

*Bennett M. Shapiro, M.D.* has been a director since May 2003. From September 1990 to July 2003, Dr. Shapiro served as an Executive Vice President of Merck & Co., Inc., a research-based pharmaceutical company. Dr. Shapiro is the former head of Worldwide Licensing and External Research at Merck; prior to that he served as the head of Basic and Preclinical Research at Merck & Co. and as Chairman of the Biochemistry department at the University of Washington. Dr. Shapiro received his B.S. in Chemistry from Dickinson College and his M.D. from Jefferson Medical College.

*Christoph H. Westphal, M.D., Ph.D.* is a co-founder and was founding Chief Executive Officer and Vice Chairman of our company and has been a director since May 2001. Dr. Westphal has served as

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the General Partner of Polaris Venture Partners, a venture capital firm, since June 2000. From July 1998 to June 2000, Dr. Westphal was a consultant at McKinsey & Co., a management consulting firm. Dr. Westphal is a member of the board of directors of Acceleron Pharma, Athenix Corporation, Saegis Pharmaceuticals, Inc., Hydra Biosciences, Inc. and Alnylam Pharmaceuticals, Inc. and is also a founder of Nanosys, Inc., among others. Dr. Westphal also founded and was Vice Chairman and founding Chief Executive Officer of Alnylam Pharmaceuticals, Inc. and Acceleron Pharma. Dr. Westphal completed his Abitur at the Deutsche Schule Washington, his B.A., *summa cum laude*, at Columbia University, and his M.D./Ph.D. at Harvard Medical School.

*John L. Zabriskie, Ph.D.* has been a director since June 2001. Dr. Zabriskie is a co-founder of PureTech Ventures, a life science venture creation and business development organization, and has served as its General Partner since April 2001. From July 1997 to August 2000, Dr. Zabriskie served as Chairman and Chief Executive Officer of NEN Life Science Products, Inc., a supplier of radioactive, chemiluminescent and fluorescent labeling and detection products for life science research and drug discovery. Prior to that, Dr. Zabriskie was President and Chief Executive Officer of Pharmacia and UpJohn, Inc. and an Executive Vice President at Merck & Co. Dr. Zabriskie is a member of the board of

directors of BioSource International, Inc., Array Biopharma, Inc., MacroChem Corporation and Kellogg Company. Dr. Zabriskie received his B.S. in Chemistry from Dartmouth College and his Ph.D. in Organic Chemistry from the University of Rochester.

*Ian D. Fier* has been our Senior Director, Development Operations since October 2002. From October 2001 to October 2002, Mr. Fier served as Vice President of Clinical Affairs for BioTransplant Incorporated, a biotechnology company, where he led the clinical development activities for both antibody based therapeutics and medical devices. From September 1997 to October 2001, Mr. Fier served as Senior Director, Product Development at The Medicines Company, a specialty pharmaceutical company focused on acute care products, where he built the development organization and managed the clinical development of bivalirudin (Angiomax®) through regulatory approval. In this role, he was responsible for managing several large clinical trials in acute coronary syndromes. Mr. Fier received his B.S. in Psychology (Biological) from Tufts University and his M.B.A. and Certificate in Health Care Management from Boston University.

### Board Composition

Upon the completion of this offering, our board of directors will consist of ten members. In accordance with the terms of our certificate of incorporation and by-laws, which will become effective upon completion of this offering, the board of directors will be divided into three classes, class I, class II and class III, with each class serving staggered three-year terms. Upon the completion of this offering, the members of the classes will be divided as follows:

- the class I directors will be Alan L. Crane, Peter Barton Hutt and Christoph H. Westphal, and their term will expire at the annual meeting of stockholders to be held in 2005;
- the class II directors will be John K. Clarke, Robert S. Langer, Jr. and Stephen T. Reeders, and their term will expire at the annual meeting of stockholders to be held in 2006; and
- the class III directors will be Peter Barrett, Ram Sasisekharan, Bennett M. Shapiro and John L. Zabriskie, and their term will expire at the annual meeting of stockholders to be held in 2007.

Our certificate of incorporation that will become effective upon the completion of this offering provides that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in the control or management of Momenta.

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Our directors may be removed only for cause by the affirmative vote of the holders of 75% or more of our voting stock.

### Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The members of each committee are appointed by the board of directors and serve one-year terms.

*Audit Committee.* We have an audit committee consisting of John K. Clarke, Stephen T. Reeders and John L. Zabriskie. John L. Zabriskie chairs the committee. The audit committee assists our board of directors in its oversight of:

- the integrity of our financial statements;
- the independent auditor's qualifications and independence; and
- the performance of our independent auditors.

The audit committee has the sole and direct responsibility for appointing, evaluating and retaining our independent auditors and for overseeing their work. All audit services to be provided to us and all non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent auditors must be approved in advance by our audit committee. We believe that each member of the audit committee satisfies the requirements for membership established by the NASDAQ National Market and the Securities and Exchange Commission.

*Compensation Committee.* We have a compensation committee consisting of Peter Barrett, Bennett M. Shapiro and Christoph H. Westphal. Peter Barrett chairs the committee. The purpose of our compensation committee is to discharge the responsibilities of our board of directors relating to compensation of our executive officers. Specific responsibilities of our compensation committee include:

- reviewing and recommending approval of compensation of our executive officers;
- administering our stock incentive and employee stock purchase plans; and
- reviewing and making recommendations to our board with respect to incentive compensation and equity plans.

We believe that each member of the compensation committee satisfies the requirements for membership established by the NASDAQ National Market.

*Nominating and Corporate Governance Committee.* We have a nominating and corporate governance committee consisting of Peter Barrett, Peter Barton Hutt and Christoph H. Westphal. Peter Barton Hutt chairs the committee. The purpose of the nominating and corporate governance committee is to:

- identify and recommend nominees for election to our board of directors;

- review and assess the adequacy of our corporate governance principles and recommend any proposed changes to our board of directors; and
- oversee the evaluation of our board.

We believe that each member of the nominating and corporate governance committee satisfies the requirements for membership established by the NASDAQ National Market.

### Director Compensation

We reimburse each member of our board of directors who is not a company employee for reasonable travel and other expenses in connection with attending meetings of the board of directors.

We have granted the following stock options under our 2002 stock incentive plan to our non-employee directors:

Name of Director	Number of Shares	Date of Grant
Peter Barton Hutt(1)	40,000	8/1/02
Peter Barton Hutt(2)	5,000	9/18/02
Peter Barton Hutt(3)	5,000	9/10/03
Bennett M. Shapiro(1)	63,438	2/5/03
John L. Zabriskie(1)	40,000	8/1/02

- (1) Twenty-five percent of the shares subject to each option vested on the first anniversary of the date of grant and the remaining shares vest at a rate of 25% annually.
- (2) This option was granted as compensation for consulting services pursuant to a consulting agreement between Mr. Hutt and us. Two thousand eighty-three shares vested on the date of grant and an additional 1/12th of the shares subject to the option vested monthly thereafter.
- (3) This option was granted as compensation for consulting services pursuant to a consulting agreement between Mr. Hutt and us. Four hundred sixteen shares vested on the the date of grant and an additional 1/12th of the shares subject to the option vest monthly thereafter.

In April 2004, our board of directors approved a program under our 2004 stock incentive plan in which each non-employee director will automatically receive an option to purchase no more than 30,000 shares of our common stock upon his or her appointment to our board of directors. These options shall vest to the extent of one-third of the shares on each of the first, second and third anniversaries of the grant date, subject to the non-employee director's continued service as a director. Subject to an annual evaluation, which evaluation shall be overseen by our Nominating and Corporate Governance Committee, each non-employee director will automatically receive an annual grant of an option to purchase no more than 15,000 shares of our common stock at each year's annual meeting after which he or she will continue to serve as a director. These options will vest on the first anniversary of the grant date, subject to the non-employee director's continued service as a director. Each non-employee director stock option will terminate on the earlier of ten years from the date of grant and three months after the recipient ceases to serve as a director, except in the case of death or disability, in which event the option will terminate three months from the date of the director's death or disability. The exercise price of all of these options will equal the fair market value of our common stock on the date of grant.

### Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, or of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the members of our compensation committee has ever been our employee.

### Scientific Advisory Board

We seek advice from a number of leading scientists and physicians on scientific and medical matters. Our scientific advisory board regularly assesses:

- our research and development programs;
- the design and implementation of our clinical programs;
- our patent and publication strategies;
- new technologies relevant to our research and development programs; and
- specific scientific and technical issues relevant to our business.

The current members of our scientific advisory board are:

Name	Professional Affiliation
Elliott Antman, M.D.	Director of Cardiac Unit, Brigham and Women's Hospital
K. Frank Austen, M.D.	Director of Inflammation and Allergic Diseases, Brigham and Women's Hospital; Professor of Medicine, Harvard Medical School
Carolyn R. Bertozzi, Ph.D.	Professor, University of California, Berkeley and Department Head of Lawrence Berkeley National Laboratory
Eugene Braunwald, M.D.	Brigham and Women's Hospital; Distinguished Hersey Professor of Medicine, Harvard Medical School; Founder and Chairman, TIMI Study Group
Frank Bullock, Ph.D.	Former Senior Vice President of Research, Schering-Plough Corporation
Benito Casu, Ph.D.	Scientific Coordinator, Ronzoni Institute for Chemical and Biochemical Research
M. Judah Folkman, M.D.	Director of Surgical Research Laboratory, Children's Hospital Boston; Professor of Pediatric Surgery, Harvard Medical School
Robert S. Langer, Jr., Sc.D.	Co-Founder of Momenta; Kenneth J. Germeshausen Professor of Chemical and Biomedical Engineering, M.I.T.
Phillips W. Robbins, Ph.D.	Professor of Molecular and Cell Biology, Boston University Medical School
Ram Sasisekharan, Ph.D.	Co-Founder of Momenta; Professor of Biological Engineering, M.I.T.

#### Regulatory Advisory Board

We seek advice from a number of leading professionals on regulatory matters. Our regulatory advisory board frequently provides advice on our proposed INDs, ANDAs and other regulatory filings. Our regulatory advisory board members also provide guidance on our communications and correspondence with regulatory agencies.

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The current members of our regulatory advisory board are:

Name	Professional Affiliation
Richard Cooper, J.D.	Williams & Connolly LLP; Former Chief Counsel, FDA
J. Richard Crout, M.D.	Former Director, Center for Drug Evaluation and Research
Thomas Q. Garvey, III, M.D.	Former Supervisory Medical Officer, Center for Drug Evaluation and Research
Peter Barton Hutt, LL.B., LL.M.	Covington & Burling; Former Chief Counsel, FDA
Robert W. Pollock	Lachman Consultant Services, Inc.; Former Deputy Director, Office of Generic Drugs, FDA

#### Executive Compensation

The table below sets forth the total compensation paid or accrued for the fiscal year ended December 31, 2003 for our chief executive officer and each of our four most highly compensated other executive officers who were serving as executive officers on December 31, 2003 and whose total annual compensation exceeded \$100,000 for the year ended December 31, 2003. We refer to these officers as our named executive officers.

#### Summary Compensation Table

Name and Principal Position	Annual Compensation		Long-Term Compensation Awards
	Salary	Bonus	Securities Underlying Options (#)
Alan L. Crane Chairman, President and Chief Executive Officer	\$ 330,555	\$ 15,000	147,500
Steven B. Brugger Vice President, Strategic Product Development	220,375	17,500	40,000
Joseph E. Tyler Vice President, Manufacturing	210,000	30,000	25,000
Susan K. Whoriskey Vice President, Licensing and Business Development	166,500	25,000	25,000

Ganesh Venkataraman Vice President, Technology	165,000	51,250	25,000
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### Option Grants in Last Fiscal Year

The following table contains information regarding grants of options to purchase shares of our common stock to our named executive officers during the year ended December 31, 2003. The potential realizable value set forth in the last column of the table is calculated based on the term of the option at the time of grant, which is ten years. This value is based on assumed rates of stock price appreciation of 5% and 10% compounded annually from the date of grant until their expiration date, assuming a fair market value equal to an assumed initial public offering price of \$ \_\_\_\_\_, minus the applicable exercise price. These numbers are calculated based on the requirements of the Securities and Exchange Commission and do not reflect our estimate of future stock price growth. Actual gains, if

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any, on stock option exercises will depend on the future performance of the common stock on the date on which the options are exercised.

Name	Number of Securities Underlying Options Granted(#)(1)	Percent of Total Options Granted to Employees in Fiscal Year(3)	Exercise Price per Share(4)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term(5)	
					5% (\$)	10% (\$)
Alan L. Crane	100,000	20.6%	\$ 0.295	06/10/2013	\$	\$
	47,500(2)	9.8	0.770	10/31/2013		
Steven B. Brugger	40,000	8.2	0.295	05/28/2013		
Joseph E. Tyler	25,000	5.2	0.295	05/28/2013		
Susan K. Whoriskey	25,000	5.2	0.295	05/28/2013		
Ganesh Venkataraman	25,000	5.2	0.295	05/28/2013		

- (1) Stock options granted to our named executive officers generally vest as to 25% of the shares on the first anniversary of the date of grant and an additional 6.25% of the shares vest at the end of each three-month period thereafter. See also footnote 2 below.
- (2) This option vests in 16 equal quarterly installments commencing on February 1, 2004.
- (3) Based on an aggregate of 485,278 shares subject to options granted to our employees in 2003, including the named executive officers.
- (4) The exercise price per share was determined to be equal to the fair market value per share of our common stock as valued by our board of directors on the date of grant.
- (5) Amounts represent hypothetical gains that could be achieved for stock options if exercised at the end of the option term. These gains are based on assumed rates of stock price appreciation of 5% and 10% compounded annually from the date stock options are granted. Actual gains, if any, on stock option exercises will depend on the future performance of our common stock on the date on which the stock options are exercised.

### Fiscal Year-End Option Values

The following table sets forth information for each of the named executive officers regarding the number of shares subject to both exercisable and unexercisable stock options, as well as the value of unexercised in-the-money options, as of December 31, 2003. There was no public trading market for our common stock as of December 31, 2003. Accordingly, we have calculated the value of the unexercised in-the-money options at fiscal year-end on the basis of an assumed fair market value of our common stock as of December 31, 2003 equal to the assumed initial public offering price of \$ \_\_\_\_\_ per

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share, less the aggregate exercise price. None of the named executive officers exercised options during the fiscal year ended December 31, 2003.

Name	Number of Securities Underlying Unexercised Options at December 31, 2003		Value of Unexercised In-The-Money Options at December 31, 2003	
	Exercisable	Unexercisable	Exercisable	Unexercisable
Alan L. Crane	—	100,000		
	—	47,500		
Steven B. Brugger	21,250	86,750		
Joseph E. Tyler	17,500	77,500		
Susan K. Whoriskey	—	25,000		
Ganesh Venkataraman	—	25,000		

## Employment Arrangements

*Alan L. Crane.* We entered into an employment agreement with Mr. Crane, our Chairman of the Board, President and Chief Executive Officer, dated March 15, 2002. Pursuant to this agreement, Mr. Crane currently receives an annual base salary of \$370,000, subject to annual increases upon review by the compensation committee of our board of directors. In connection with the execution of the agreement, we paid Mr. Crane a bonus of \$106,585.

Under the agreement, either we or Mr. Crane may terminate his employment at any time, subject to continuation of salary payment and benefits for one year if we terminate Mr. Crane's employment without cause or Mr. Crane terminates his employment for good reason. If, however, Mr. Crane commences full-time employment or enters into a consulting arrangement during the period of time for which we are providing severance benefits to Mr. Crane, then our cash severance payments to Mr. Crane will be reduced by the amount of any cash compensation Mr. Crane earns in his new employment or consulting arrangement. In addition, we will have no obligation to provide for benefits so long as the quality of the benefits provided by the new employer are equivalent or superior to the benefits provided by us.

In connection with the execution of a restricted stock agreement dated March 15, 2002, Mr. Crane purchased 766,296 shares of restricted common stock for an aggregate purchase price of \$106,662. Subject to certain vesting conditions, the 766,296 shares of restricted common stock are subject to a repurchase right by us at a per share price of \$0.17. Mr. Crane agreed to pay the purchase price to us in three installments on each of January 1, 2003, January 1, 2004 and January 1, 2005.

*Susan K. Whoriskey.* We entered into an employment agreement with Dr. Whoriskey, our Vice President, Licensing and Business Development, dated April 10, 2002. Pursuant to this agreement, Dr. Whoriskey currently receives an annual base salary of \$180,000, subject to increases upon review at least once every six months.

Under the agreement, either we or Dr. Whoriskey may terminate her employment at any time, subject to continuation of salary payment and benefits for three months if we terminate Dr. Whoriskey's employment without cause or Dr. Whoriskey terminates her employment for good reason.

*Ganesh Venkataraman.* We entered into an employment agreement with Dr. Venkataraman, our Vice President, Technology, dated June 13, 2001, which was amended and restated on April 10, 2002. Pursuant to this agreement, Dr. Venkataraman currently receives an annual base salary of \$205,000, subject to increases upon review at least once every 12 months.

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Under the agreement, as amended, either we or Dr. Venkataraman may terminate his employment at any time, subject to continuation of salary payment and benefits for three months if we terminate Dr. Venkataraman's employment without cause or Dr. Venkataraman terminates his employment for good reason.

Our employment agreements with Mr. Crane, Dr. Whoriskey and Dr. Venkataraman contain nondisclosure, noncompetition and assignment of intellectual property terms. These terms provide for the protection of our confidential information, the transfer of ownership rights to intellectual property developed by such executive officer and a 12-month noncompete provision. Each of our other executive officers has signed our standard form of nondisclosure, noncompetition and assignment of intellectual property agreement, providing for the protection of our confidential information, the transfer of ownership rights to intellectual property developed by such executive officer and an 18-month noncompete provision.

## Stock Option and Other Compensation Plans

### 2002 Stock Incentive Plan

Our 2002 stock incentive plan was adopted by our board of directors and approved by our stockholders in December 2001. In September 2002 and December 2002, our board of directors and stockholders approved amendments to the 2002 stock incentive plan. The 2002 stock incentive plan, as amended, provides for the grant of incentive stock options, non-statutory stock options and restricted stock awards. A maximum of 1,028,662 shares of common stock are authorized for issuance under our 2002 stock incentive plan.

In accordance with the terms of the 2002 stock incentive plan, our board of directors has authorized our compensation committee to administer the 2002 stock incentive plan.

Upon a merger or other reorganization event, our board of directors, or the board of directors of any corporation assuming our obligations, may, in their sole discretion, take any one or more of the following actions pursuant to our 2002 stock incentive plan, as to some or all outstanding options:

- provide that all outstanding options shall be assumed or substituted by the successor corporation;
- terminate all unexercised outstanding options immediately prior to the consummation of such transaction unless exercised by the optionee;
- in the event of a merger pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the merger, make or provide for a cash payment to the optionees equal to the difference between the merger price times the number of shares of our common stock subject to such outstanding options (to the extent then exercisable at prices not in excess of the merger price), and the aggregate exercise price of all such outstanding options, in exchange for the termination of such options; and
- provide that all or any outstanding options shall become exercisable in full immediately prior to such event.

Pursuant to our 2002 stock incentive plan, upon a merger or other reorganization event, any securities, cash or other property received in exchange for shares of restricted stock shall continue to be governed by the provisions of any restricted stock agreement pursuant to which such restricted stock was issued.

As of March 1, 2004, there were options to purchase 797,605 shares of common stock outstanding under the 2002 stock incentive plan, and

previously exercised options. After the effective date of the 2004 stock incentive plan described below, we will grant no further stock options or other awards under the 2002 stock incentive plan.

#### **2004 Stock Incentive Plan**

Our 2004 stock incentive plan was adopted by our board of directors on March 8, 2004 and approved by our stockholders on 2004. The 2004 stock incentive plan will become effective on the date that the registration statement of which this prospectus forms a part is declared effective. The 2004 stock incentive plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. Upon effectiveness, 3,084,988 shares of common stock will be reserved for issuance under the 2004 stock incentive plan. In addition, the 2004 stock incentive plan contains an "evergreen provision" which allows for an annual increase in the number of shares available for issuance under the plan on the first day of each of our fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013. The annual increase in the number of shares shall be equal to the lowest of

- 1,542,494 shares;
- 5% of our outstanding shares on the first day of the fiscal year; and
- an amount determined by our board of directors.

Under this provision, no annual increase shall be made to the extent that the number of shares of common stock available for issuance under the 2004 stock incentive plan and all other employee or director equity incentive plans, including our 2004 employee stock purchase plan, would exceed 25% of our outstanding shares on the first day of the applicable fiscal year.

In accordance with the terms of the 2004 stock incentive plan, our board of directors has authorized our compensation committee to administer the 2004 stock incentive plan. In accordance with the provisions of the 2004 stock incentive plan, our compensation committee will select the recipients of awards and determine:

- the number of shares of common stock covered by options and the dates upon which the options become exercisable;
- the exercise price of options;
- the duration of options;
- the method of payment of the exercise price; and
- the number of shares of common stock subject to any restricted stock or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price.

In addition, our board of directors or any committee to which the board of directors delegates authority may, with the consent of the affected plan participants, amend outstanding awards.

Upon a merger or other reorganization event, our board of directors, may, in their sole discretion, take any one or more of the following actions pursuant to our 2004 stock incentive plan, as to some or all outstanding awards:

- provide that all outstanding awards shall be assumed or substituted by the successor corporation;
- upon written notice to a participant, provide that the participant's unexercised options or awards will become exercisable in full and will terminate immediately prior to the consummation of such transaction unless exercised by the participant;

- provide that outstanding awards become realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event;
- in the event of a merger pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the merger, make or provide for a cash payment to the participants equal to the difference between the merger price times the number of shares of our common stock subject to such outstanding awards (to the extent then exercisable at prices not in excess of the merger price), and the aggregate exercise price of all such outstanding awards, in exchange for the termination of such awards; and
- provide that, in connection with a liquidation or dissolution, awards convert into the right to receive liquidation proceeds.

#### **2004 Employee Stock Purchase Plan**

Our 2004 employee stock purchase plan was adopted by our board of directors on March 8, 2004 and approved by our stockholders on 2004. The 2004 employee stock purchase plan will become effective on the date that the registration statement of which this prospectus forms a part is declared effective. The plan provides for the issuance of up to 409,884 shares of common stock to participating employees.

All of our employees, including directors who are employees, and all employees of any participating subsidiaries:

- whose customary employment is more than 20 hours per week for more than five months in a calendar year;
- who were employed by us for at least 90 days prior to enrolling; and
- who are employed on the first day of a designated payroll deduction offering period are eligible to participate in the 2004 employee stock purchase plan.

Employees who would immediately after the grant of an option under the 2004 employee stock purchase plan own 5% or more of the total combined voting power or value of our stock or the stock of any of our subsidiaries are not eligible to participate in the purchase plan.

We will make one or more offerings to our employees to purchase stock under the 2004 employee stock purchase plan. Offerings will begin on each February 1, except that our first offering commencement date will begin on the date on which trading of our common stock commences on the NASDAQ National Market in connection with this offering. Each offering commencement date will begin a twelve-month period during which payroll deductions will be made and held for the purchase of our common stock at the end of the purchase plan period.

On the first day of a designated payroll deduction period, or offering period, we will grant to each eligible employee who has elected to participate in the purchase plan an option to purchase shares of our common stock as follows: the employee may authorize up to 15% of his or her base pay to be deducted by us during the offering period. On the last day of the offering period, the employee is deemed to have exercised the option, at the option exercise price, to the extent of accumulated payroll deductions. Under the terms of the 2004 employee stock purchase plan, the option exercise price is an amount equal to 85% of the lower of the closing price of our common stock on the first day or the last day of the offering period. For purposes of the first offering period under the purchase plan, the closing price of our common stock on the first day of such period is deemed to equal the initial public offering price per share in this offering.

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In no event may an employee purchase in any one offering period a number of shares which exceeds the number of shares determined by dividing:

- the product of \$2,083 and the number of full months in the offering period, by
- the closing price of a share of our common stock on the commencement date of the offering period.

Our board of directors may, in its discretion, choose a different offering period for each subsequent offering.

An employee who is not a participant on the last day of the offering period is not entitled to exercise any option, and the employee's accumulated payroll deductions will be refunded. An employee's rights under the 2004 employee stock purchase plan terminate upon voluntary withdrawal from the purchase plan at any time, or when the employee ceases employment for any reason, except that upon termination of employment because of death, the balance in the employee's account will be paid to the employee's beneficiary.

Because participation in the purchase plan is voluntary, we cannot now determine the number of shares of our common stock to be purchased by any particular current executive officer, by all current executive officers as a group or by non-executive employees as a group.

#### **401(k) Plan**

We maintain a retirement and deferred savings plan for our employees. The retirement and deferred savings plan is intended to qualify as a tax-qualified plan under Section 401 of the Code. The retirement and deferred savings plan provides that each participant may contribute up to 15% of his or her pre-tax compensation, up to a statutory limit, which for most employees is \$13,000 in 2004. Under the plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan's trustee. The retirement and deferred savings plan also permits us to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. To date, we have not made any discretionary contributions to the retirement and deferred savings plan on behalf of participating employees.

#### **Limitation of Liability and Indemnification of Officers and Directors**

Our certificate of incorporation that will be in effect upon completion of this offering limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law. Our certificate of incorporation provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of their duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for voting or assenting to unlawful payments of dividends or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act or failure to act, or any cause of action, suit or claim that would accrue or arise prior to any amendment or repeal or adoption of an inconsistent provision. If the Delaware General Corporation Law is amended to provide for further limitations on the personal liability of

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directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the Delaware General Corporation Law.

In addition, our certificate of incorporation provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

In addition to the indemnification provided for in our certificate of incorporation, we expect to enter into separate indemnification agreements with each of our directors and executive officers which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers. There is no pending litigation or proceeding involving any of our directors or executive officers to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

#### Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Since our incorporation in May 2001, we have engaged in the following transactions with our directors and officers and holders of more than five percent of our voting securities and affiliates of our directors, officers and holders of more than five percent of our voting securities:

#### Stock Issuances

##### *Issuances of Restricted Common Stock*

In June 2001, in connection with our formation, we issued an aggregate of 2,070,314 shares of restricted common stock at a price per share of \$0.0001 to the following directors, officers and holders of more than five percent of our voting securities.

Name	Number of Shares of Common Stock	Aggregate Purchase Price
Robert S. Langer, Jr.	809,800	\$ 80.98
Ram Sasisekharan	809,800	80.98
Ganesh Venkataraman	380,400	38.04
Alan L. Crane	23,438	2.34
Peter Barton Hutt	23,438	2.34
Lansing Brown Investments, LLC (John L. Zabriskie)	23,438	2.34

In March 2002 and April 2002, we issued an aggregate of 836,773 shares of restricted common stock at a price per share of \$0.14 and \$0.17, respectively, to the following director and officer.

Name	Number of Shares of Common Stock	Aggregate Purchase Price
Alan L. Crane	766,296	\$ 106,662.00*
Susan K. Whoriskey	70,477	11,981.09

\* Mr. Crane agreed to pay the purchase price in three installments on each of January 1, 2003, January 1, 2004 and January 1, 2005.

##### *Issuance of Series A Convertible Preferred Stock and Warrants to Purchase Series A Prime Convertible Preferred Stock*

On August 16, 2001, we sold an aggregate of 250,000 shares of Series A convertible preferred stock at a price per share of \$1.00 for an aggregate purchase price of \$250,000, together with warrants to purchase an aggregate of 585,926 shares of our Series A prime convertible preferred stock with an exercise price per share of \$1.7067. All shares of our Series A convertible preferred stock will be automatically converted into 250,000 shares of our common stock upon completion of this offering. Of these 250,000 shares, an aggregate of 230,000 shares, together with warrants to purchase 539,052 shares of our Series A prime convertible preferred stock, were sold to the following holders of more than five percent of our voting securities and its affiliates.

Name	Number of Shares of Series A Convertible Preferred Stock	Number of Shares of Series A Prime Convertible Preferred Stock Underlying Warrants	Aggregate Purchase Price
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Polaris Venture Partners III, L.P. and related entities (Christoph H. Westphal)	230,000	539,052	\$	230,000
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#### **Issuance of Series A Prime Convertible Preferred Stock**

On January 24, 2002, we sold an aggregate of 893,537 shares of Series A prime convertible preferred stock, 539,052 of which were issued pursuant to the exercise of warrants issued to Polaris Venture Partners III, L.P. and related entities on August 16, 2001, at a price per share of \$1.7067 for an aggregate purchase price of \$1,524,999. All shares of our Series A prime convertible preferred stock will be automatically converted into 893,537 shares of our common stock upon completion of this offering. Of these 893,537 shares, an aggregate of 763,212 shares were sold to the following directors, officers and holders of more than five percent of our voting securities and their affiliates.

Name	Number of Shares of Series A Prime Convertible Preferred Stock	Aggregate Purchase Price
Polaris Venture Partners III, L.P. and related entities (Christoph H. Westphal)	572,786	\$ 977,573.87
Lansing Brown Investments, LLC (John L. Zabriskie)	58,593	100,000.67
Alan L. Crane	58,593	100,000.67
Peter Barton Hutt	29,296	49,999.48
Robert S. Langer, Jr.	29,296	49,999.48
Susan K. Whoriskey	14,648	24,999.74

#### **Issuance of Series A Double Prime Convertible Preferred Stock**

On April 16, 2002, we sold an aggregate of 1,533,101 shares of Series A double prime convertible preferred stock at a price per share of \$2.87 for an aggregate purchase price of \$4,400,000. All shares of our Series A double prime convertible preferred stock will be automatically converted into 1,533,101 shares of our common stock upon completion of this offering. Of these 1,533,101 shares, an aggregate of 1,515,679 shares were sold to the following holders of more than five percent of our voting securities and their affiliates.

Name	Number of Shares of Series A Double Prime Convertible Preferred Stock	Aggregate Purchase Price
Polaris Venture Partners III, L.P. and related entities (Christoph H. Westphal)	1,132,404	\$ 3,249,999.48
CHP II, L.P. (John K. Clarke)	348,432	999,999.84
Lansing Brown Investments, LLC (John L. Zabriskie)	34,843	99,999.41

#### **Issuance of Series B Convertible Preferred Stock**

On May 9, 2003, we sold an aggregate of 6,440,678 shares of Series B convertible preferred stock at a price per share of \$2.95 for an aggregate purchase price of \$19,000,000. All shares of our Series B convertible preferred stock will be automatically converted into 6,440,678 shares of our common stock

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upon completion of this offering. The entire 6,440,678 shares were sold to the following holders of more than five percent of our voting securities and their affiliates.

Name	Number of Shares of Series B Convertible Preferred Stock	Aggregate Purchase Price
Atlas Venture entities (Peter Barrett)	2,415,254	\$ 7,124,999.30
MVM International Life Sciences Fund No. 1 L.P. and related entities and individuals (Stephen T. Reeders)	1,779,661	5,249,999.95
Polaris Venture Partners III, L.P. and related entities (Christoph H. Westphal)	1,271,186	3,749,998.70
CHP II, L.P. (John K. Clarke)	974,577	2,875,002.15

#### **Issuance of Series C Convertible Preferred Stock**

On February 27, 2004, we sold an aggregate of 2,612,696 shares of Series C convertible preferred stock at a price per share of \$7.8463 for an aggregate purchase price of \$20,499,996.62. All shares of our Series C convertible preferred stock will be automatically converted into 2,612,696 shares of our common stock upon completion of this offering. Of these 2,612,696 shares, an aggregate of 2,612,696 shares were sold to the following holders of more than five percent of our voting securities and their affiliates.

Name	Number of Shares of Series C Convertible Preferred Stock	Aggregate Purchase Price
Mithra Ventures, L.P.	881,788	\$ 6,918,773.18
Polaris Venture Partners III, L.P. and related entities (Christoph H. Westphal)	613,247	4,811,719.94

Atlas Venture entities (Peter Barrett)	460,053	3,609,713.85
MVM International Life Sciences Fund No. 1 L.P. and related entities and individuals (Stephen T. Reeders)	338,986	2,659,785.85
CHP II, L.P. (John K. Clarke)	318,622	2,500,003.80

### **Certain Relationships**

#### ***Consulting Agreement with Robert S. Langer, Jr.***

In July 2001, we entered into a consulting agreement with Robert S. Langer, Jr., one of our founders and a member of our board of directors, pursuant to which Dr. Langer provides consulting services as reasonably requested by us from time to time. The term of the consulting agreement was initially for two years, has been renewed for a one-year term and may be renewed for additional one-year terms by mutual agreement of us and Dr. Langer. Under the terms of the agreement, we provide compensation to Dr. Langer of up to \$25,000, \$50,000 or \$100,000 on an annual basis contingent upon the achievement of certain milestones. We paid Dr. Langer \$32,260 for consulting services in 2003. On or after the consummation by us of an initial public offering, we will pay Dr. Langer \$100,000 as compensation for his services under the agreement.

#### ***Consulting Agreement with Ram Sasisekharan***

In August 2001, we entered into a consulting agreement with Ram Sasisekharan, one of our founders and a member of our board of directors, pursuant to which Dr. Sasisekharan provides consulting services as mutually determined by us and Dr. Sasisekharan from time to time. The term of the consulting agreement was initially for two years, has been renewed for a one-year term and may be renewed for additional one-year terms by mutual agreement of us and Dr. Sasisekharan. Under the terms of the agreement, we provide compensation to Dr. Sasisekharan of up to \$25,000, \$50,000 or

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\$100,000 on an annual basis contingent upon the achievement of certain milestones. We paid Dr. Sasisekharan \$71,668 for consulting services in 2003. On or after the consummation by us of an initial public offering, we will pay Dr. Sasisekharan \$100,000 as compensation for his services under the agreement.

#### ***Consulting Agreement with Peter Barton Hutt***

In September 2002, we entered into a consulting agreement with Peter Barton Hutt, a member of our board of directors, pursuant to which Mr. Hutt provides consulting and advisory services relating to the field of regulatory strategies for drug development. The consulting agreement provides for no more than an average of one day of service per month. The term of the consulting agreement was initially for one year, has been renewed for a one-year term and may be renewed for additional one-year terms by mutual agreement of us and Mr. Hutt. Under the terms of the agreement, as extended, in 2002 we granted Mr. Hutt a non-statutory stock option to purchase 5,000 shares of our common stock at a purchase price of \$0.29 per share valued at \$8,600 and a non-statutory stock option to purchase 5,000 shares of our common stock at a purchase price of \$0.295 per share valued at \$8,875.

Each of the above-mentioned consulting agreements were entered into on terms as favorable as could have been obtained by unrelated third parties.

#### ***Purchase of Restricted Stock by Alan L. Crane***

In connection with the execution of a restricted stock agreement effective March 15, 2002, Mr. Crane purchased 766,296 shares of restricted common stock for an aggregate purchase price of \$106,662. Subject to certain vesting conditions, the 766,296 shares of restricted common stock issued to Mr. Crane are subject to a repurchase right by us at a per share price of \$0.17. Mr. Crane agreed to pay the purchase price to us in three installments on each of January 1, 2003, January 1, 2004 and January 1, 2005.

#### ***Alan L. Crane Relationship with Polaris Venture Partners***

Mr. Crane has served as a venture partner of Polaris Venture Partners since 2002 and holds a carried interest in Polaris Venture Partners III and Polaris Venture Partners IV, each of which is an affiliate of a stockholder of Momenta. Until May 2003, Mr. Crane received compensation from Polaris Venture Partners, including \$35,000 in 2003.

#### ***Reallocation of Founder Shares***

Pursuant to the terms of a Reallocation of Founder Shares Agreement dated April 10, 2002, each of Robert S. Langer, Jr. and Ram Sasisekharan transferred 40,000 shares of restricted common stock to Ganesh Venkataraman.

#### ***Ram Sasisekharan Relationship with Data Integration Provider***

Ram Sasisekharan, one of our co-founders and a member of our board of directors, is the brother of Sasisekharan Raguram, who is the chief technical officer of Parivid, LLC, a company that provides data integration services to us.

#### ***Director Compensation***

Please see "Management—Director Compensation" for a discussion of options granted to our non-employee directors.

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### ***Executive Compensation and Employment Arrangements***

Please see "Management—Executive Compensation" and "Management—Option Grants in Last Fiscal Year" for additional information on compensation of our executive officers. Information regarding employment arrangements with several of our executive officers is set forth under "Management—Employment Arrangements."

### Registration Rights

Upon completion of this offering, the holders of 14,532,246 shares of our common stock, including a warrant exercisable to purchase 12,500 shares of common stock, are entitled to register their shares under the Securities Act. These rights are provided under the terms of an investors' rights agreement between us and these holders. These holders include the following directors, officers and holders of more than five percent of our voting securities and their affiliates:

Name of Holder	Number of Registrable Shares
Alan L. Crane and affiliates	848,327
Ganesh Venkataraman	460,400
Susan K. Whoriskey	14,648
Peter Barton Hutt	29,296
Robert S. Langer, Jr. and affiliates	799,096
Ram Sasisekharan	769,800
Lansing Brown Investments, LLC (John L. Zabriskie)	93,436
Polaris Venture Partners III, L.P. and related entities (Christoph H. Westphal)	3,832,763
Atlas Venture entities (Peter Barrett)	2,875,307
MVM International Life Sciences Fund No. 1 L.P. and related entities and individuals (Stephen T. Reeders)	2,118,647
CHP II, L.P. (John K. Clarke)	1,641,631
Mithra Ventures, L.P.	881,788
<b>Total:</b>	<b>14,365,139</b>

The holders of these registration rights have waived their right to participate in this offering.

### PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 1, 2004, by:

- each of our directors;
- each of our named executive officers;
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock; and
- all of our directors and executive officers as a group.

The column entitled "Percentage of Shares Beneficially Owned—Before Offering" is based on 15,004,080 shares of common stock outstanding as of March 1, 2004, assuming conversion of all outstanding shares of convertible preferred stock, but assuming no exercise of outstanding warrants or options. The column entitled "Percentage of Shares Beneficially Owned—After Offering" is based on shares of common stock to be outstanding after this offering, including the shares that we are selling in this offering, but not including any shares issuable upon exercise of warrants or options.

For purposes of the table below, we deem shares subject to options or warrants that are currently exercisable or exercisable within 60 days of March 1, 2004 to be outstanding and to be beneficially owned by the person holding the options for the purpose of computing the percentage ownership of that person but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. Except as otherwise noted, the persons or entities in this table have sole voting and investing power with respect to all of the shares of common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the street address of the beneficial owner is c/o Momenta Pharmaceuticals, Inc., 43 Moulton Street, Cambridge, Massachusetts 02138.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>Holders of more than 5% of our voting securities</b>			
Polaris Venture Partners III, L.P. and related entities Bay Colony Corporate Center 1000 Winter Street, Suite 3350 Waltham, MA 02457	3,832,763(1)	25.5%	
Atlas Venture entities 890 Winter Street, Suite 320 Waltham, MA 02451	2,875,307(2)	19.2%	

MVM International Life Sciences Fund No. 1 L.P. and related entities and individuals 6 Henrietta Street London WC2E 8PU CHP II, L.P.	2,118,647(3)	14.1%
c/o Cardinal Partners 221 Nassau Street Princeton, NJ 08542 Mithra Ventures, L.P.	1,641,631(4)	10.9%
205 Newbury Street, 3 <sup>rd</sup> Floor Boston, MA 02116 Alan L. Crane	881,788(5)	5.9%
Ram Sasisekharan	812,625(6)	5.4%
Robert S. Langer, Jr.	769,800(7)	5.1%
	763,096(8)	5.1%

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Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>Directors and named executive officers</b>			
Peter Barrett	2,875,307(2)	19.2%	
John K. Clarke	1,641,631(4)	10.9%	
Peter Barton Hutt	70,650(9)	*	
Robert S. Langer, Jr.	763,096(8)	5.1%	
Stephen T. Reeders	2,118,647(3)	14.1%	
Ram Sasisekharan	769,800(7)	5.1%	
Bennett M. Shapiro	—	—	
Christoph H. Westphal	3,832,763(1)	25.5%	
John L. Zabriskie	126,874(10)	*	
Alan L. Crane	812,625(6)	5.4%	
Steven B. Brugger	25,500(11)	*	
Ganesh Venkataraman	460,400(12)	3.1%	
Susan K. Whoriskey	88,058(13)	*	
Joseph E. Tyler	21,875	*	
<b>All directors and executive officers as a group (15 persons)</b>	<b>13,607,226(14)</b>	<b>90.4%</b>	

\* Represents beneficial ownership of less than one percent of common stock.

- (1) Consists of (a) 3,679,240 shares of common stock held by Polaris Venture Partners III, L.P. issuable upon the automatic conversion of preferred stock upon the completion of this offering, (b) 95,531 shares of common stock held by Polaris Venture Partners Entrepreneurs' Fund III, L.P. issuable upon the automatic conversion of preferred stock upon the completion of this offering and (c) 57,992 shares of common stock held by Polaris Venture Partners Founders' Fund III, L.P. issuable upon the automatic conversion of preferred stock upon the completion of this offering. Polaris Venture Management Co. III, L.L.C. is the general partner of Polaris Venture Partners III, L.P., Polaris Venture Partners Entrepreneurs' Fund III, L.P. and Polaris Venture Partners Founders' Fund III, L.P. The managing members of Polaris Venture Management Co. III, L.L.C. are Stephen D. Arnold, Jonathan A. Flint, Terrance G. McGuire and Alan G. Spoon, which individuals may be deemed to have shared voting, investment and dispositive power with respect to these shares. Christoph H. Westphal, a director of Momenta, is a non-managing member of Polaris Venture Management Co. III, L.L.C. Dr. Westphal disclaims beneficial ownership of these shares except to the extent of his proportionate pecuniary interest in such shares.
- (2) Consists of (a) 909,132 shares of common stock held by Atlas Venture Fund V, L.P. issuable upon the automatic conversion of preferred stock upon completion of this offering, (b) 112,929 shares of common stock held by Atlas Venture Parallel Fund V-A, C.V. issuable upon the automatic conversion of preferred stock upon completion of this offering, (c) 112,929 shares of common stock held by Atlas Venture Parallel Fund V-B, C.V. issuable upon the automatic conversion of preferred stock upon completion of this offering, (d) 15,132 shares of common stock held by Atlas Venture Entrepreneurs' Fund V, L.P. issuable upon the automatic conversion of preferred stock upon completion of this offering, (e) 1,644,770 shares of common stock held by Atlas Venture Fund VI, L.P. issuable upon the automatic conversion of preferred stock upon completion of this offering, (f) 50,298 shares of common stock held by Atlas Venture Entrepreneurs' Fund VI, L.P. issuable upon the automatic conversion of preferred stock upon completion of this offering and (g) 30,117 shares of common stock held by Atlas Venture Fund VI GmbH & Co. KG issuable upon the automatic conversion of preferred stock upon completion of this offering. Atlas Venture Associates V, L.P. is the general partner of Atlas Venture Fund V, L.P., Atlas Venture Parallel Fund V-A, C.V., Atlas Venture Parallel Fund V-B, C.V. and Atlas Venture Entrepreneurs' Fund V, L.P. Atlas Venture Associates VI, L.P. is the general partner of Atlas Venture Fund VI, L.P. and Atlas Venture Entrepreneurs' Fund VI, L.P. and the managing limited partner of Atlas Venture Fund VI GmbH & Co. KG. Christopher Spray, Axel Bichara and Jean-François Formela are the

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members of the board of management of each of Atlas Venture Associates V, L.P. and Atlas Venture Associates VI, L.P. and exercise voting, investment and dispositive rights with respect to the shares of stock held by each of the Atlas Venture entities identified in this footnote. Each of Messrs. Spray, Bichara and Formela disclaims beneficial ownership of these shares except to the extent of his respective proportionate pecuniary interest therein. Peter J. Barrett, a director of Momenta, is a special limited partner of Atlas Venture

Associates V, L.P. and Atlas Venture Associates VI, L.P. Dr. Barrett disclaims beneficial ownership of the shares held by the Atlas Venture entities except to the extent of his proportionate pecuniary interest therein.

- (3) Consists of (a) 2,097,460 shares of common stock held by MVM International Life Sciences Fund No. 1 L.P. issuable upon the automatic conversion of preferred stock upon the completion of this offering, (b) 6,763 shares of common stock held by MVM Limited issuable upon the automatic conversion of preferred stock upon the completion of this offering, (c) 4,661 shares of common stock held by Stephen T. Reeders issuable upon the automatic conversion of preferred stock upon completion of this offering, (d) 4,661 shares of common stock held by David Brister issuable upon the automatic conversion of preferred stock upon completion of this offering, (e) 4,661 shares of common stock held by Paul Triniman issuable upon the automatic conversion of preferred stock upon the completion of this offering, (f) 75 shares of common stock held by Martin Murphy issuable upon the automatic conversion of preferred stock upon completion of this offering, (g) 183 shares of common stock held by Richard Lim issuable upon the automatic conversion of preferred stock upon completion of this offering and (h) 183 shares of common stock held by Thomas Casdagli issuable upon the automatic conversion of preferred stock upon completion of this offering. Stephen Reeders, Paul Triniman and David Brister are the investment directors of MVM Limited, which individuals exercise discretionary investment power over securities held by MVM International Life Sciences Fund No. 1 L.P., MVM Limited, Stephen Reeders, Paul Triniman, David Brister, Martin Murphy, Richard Lim and Thomas Casdagli, and are principally responsible for the selection, acquisition and disposition of these securities. Dr. Reeders, a director of Momenta, disclaims beneficial ownership of these shares except to the extent of his proportionate pecuniary interest in such shares.
- (4) Consists of 1,641,631 shares of common stock held by CHP II, L.P. issuable upon the automatic conversion of preferred stock upon completion of this offering. John K. Clarke, a director of Momenta, Brandon H. Hull, Lisa Skeete Tatum and John J. Park are the managing members of CHP II Management, LLC, the General Partner of CHP II, L.P., and exercise shared voting, investment, and dispositive rights with respect to the shares of stock held by CHP II, L.P. Each of Messrs. Clarke, Hull and Park and Ms. Skeete Tatum disclaims beneficial ownership of the shares identified in this footnote except as to his or her respective proportionate pecuniary interest in such shares.
- (5) Consists of 881,788 shares of common stock issuable upon the automatic conversion of preferred stock upon the completion of this offering. Farah Ebrahimi and Nina Ross, the managing members of the general partner of Mithra Ventures, L.P., exercise shared voting and investment power with respect to the shares owned by Mitra Ventures, L.P. Each of Ms. Ebrahimi and Ms. Ross disclaim beneficial ownership of such shares except to the extent of her respective pecuniary interest therein.
- (6) Consists of (a) 19,923 shares of common stock issuable upon the automatic conversion of preferred stock upon the completion of this offering, (b) 789,734 shares of restricted common stock, of which 390,473 shares remain subject to a repurchase right by us pursuant to restricted stock agreements between us and Mr. Crane and (c) 2,968 shares of common stock underlying options exercisable within 60 days of March 1, 2004.
- (7) Consists of 769,800 shares of restricted common stock, of which 240,563 shares remain subject to a repurchase right by us pursuant to a restricted stock agreement between us and Dr. Sasisekharan.
- (8) Consists of (a) 29,296 shares of common stock issuable upon the automatic conversion of preferred stock upon the completion of this offering and (b) 733,800 shares of restricted common

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stock, of which 240,563 shares remain subject to a repurchase right by us pursuant to a restricted stock agreement between us and Dr. Langer.

- (9) Consists of (a) 29,296 shares of common stock issuable upon the automatic conversion of preferred stock upon the completion of this offering, (b) 23,438 shares of restricted common stock, of which 7,325 shares remain subject to a repurchase right by us pursuant to a restricted stock agreement between us and Mr. Hutt and (c) 17,916 shares of common stock underlying options exercisable within 60 days of March 1, 2004.
- (10) Consists of (a) 93,436 shares of common stock held by Lansing Brown Investments, LLC issuable upon the automatic conversion of preferred stock upon the completion of this offering, (b) 23,438 shares of restricted common stock held by Lansing Brown Investments, LLC, of which 7,325 shares remain subject to a repurchase right by us pursuant to a restricted stock agreement between us and Lansing Brown Investments, LLC and (c) 10,000 shares of common stock underlying options held by John L. Zabriskie exercisable within 60 days of March 1, 2004. Dr. Zabriskie, a director of Momenta, is the president of Lansing Brown Investments, LLC and disclaims beneficial ownership of shares held by Lansing Brown Investment, LLC except to the extent of his proportionate pecuniary interest in such shares.
- (11) Consists of 25,500 shares of common stock underlying options exercisable within 60 days of March 1, 2004.
- (12) Consists of 460,400 shares of restricted common stock, of which 143,875 shares remain subject to a repurchase right by us pursuant to a restricted stock agreement between us and Dr. Venkataraman.
- (13) Consists of (a) 14,648 shares of common stock issuable upon the automatic conversion of preferred stock upon the completion of this offering and (b) 73,410 shares of restricted common stock, of which 33,695 shares remain subject to a repurchase right by us pursuant to a restricted stock agreement between us and Dr. Whoriskey.
- (14) See footnotes 1-4 and 6-13 above.

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The following description of our capital stock and provisions of our certificate of incorporation and by-laws are summaries and are qualified by reference to the certificate of incorporation and the by-laws that will be in effect upon the completion of this offering. Copies of these documents have been filed with the Securities and Exchange Commission as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the completion of this offering.

Upon the completion of this offering, our authorized capital stock will consist of 100,000,000 shares of common stock, par value \$0.0001 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share, all of which preferred stock will remain undesignated.

As of March 1, 2004, we had issued and outstanding:

- 3,274,068 shares of common stock, held by 39 stockholders of record;
- 250,000 shares of Series A convertible preferred stock, held by 4 stockholders of record;
- 893,537 shares of Series A prime convertible preferred stock, held by 12 stockholders of record;
- 1,533,101 shares of Series A double prime convertible preferred stock, held by 6 stockholders of record;
- 6,440,678 shares of Series B convertible preferred stock, held by 16 stockholders of record; and
- 2,612,696 shares of Series C convertible preferred stock, held by 20 stockholders of record.

As of March 1, 2004, we also had outstanding a warrant to purchase 12,500 shares of Series A double prime convertible preferred stock at an exercise price of \$2.87.

Upon the completion of this offering, all of the outstanding shares of our preferred stock will automatically convert into a total of 11,730,012 shares of our common stock. In addition, upon completion of this offering, a warrant to purchase an aggregate of 12,500 shares of Series A double prime convertible preferred stock will remain outstanding and will be exercisable for 12,500 shares of common stock at an exercise price of \$2.87 per share. If this warrant is exercised for cash, we would issue an aggregate of 12,500 shares of common stock for cash proceeds of approximately \$35,875.

#### **Common Stock**

Holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Accordingly, holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to receive proportionately our net assets available after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

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#### **Preferred Stock**

Under the terms of our certificate of incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon completion of this offering, there will be no shares of preferred stock outstanding and we have no present plans to issue any shares of preferred stock.

#### **Warrants**

Upon completion of this offering, we will have an outstanding warrant to purchase 12,500 shares of our common stock at an exercise price of \$2.87 per share. The warrant expires on December 27, 2012 and provides for assumption and/or adjustments in the event of specified mergers, reorganizations, reclassifications, stock dividends, stock splits or other changes in our corporate structure.

#### **Options**

As of March 1, 2004, options to purchase 797,605 shares of common stock at a weighted average exercise price of \$0.38 per share were outstanding.

#### **Antitakeover Provisions**

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly-held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors or unless the

business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger or consolidation involving us, and the interested stockholder and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

Our certificate of incorporation and our by-laws divide our board of directors into three classes with staggered three-year terms. In addition, our certificate of incorporation and our by-laws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% or more of our shares of capital stock present in person or by proxy and entitled to vote. Under our certificate of incorporation and by-laws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Our certificate of incorporation and our by-laws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a

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meeting. Our certificate of incorporation and our by-laws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our chairman of the board, our chief executive officer or our board of directors. In addition, our by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of our outstanding voting securities until the next stockholder meeting.

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our by-laws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders of at least 75% of the votes which all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes which all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described in the prior two paragraphs.

#### **Registration Rights**

Upon the completion of this offering, holders of an aggregate of approximately 14,532,246 shares of our common stock, including a warrant exercisable to purchase 12,500 shares of common stock, will have the right to require us to register these shares under the Securities Act under specific circumstances.

*Demand registration rights.* At any time after the earlier of May 9, 2006 and six months after this offering, subject to specified limitations, these stockholders may require that we register on not more than two occasions all or part of these securities for sale under the Securities Act. Once we are qualified to use Form S-3, holders of these shares may make demands for registrations on Form S-3 on up to two occasions during any 12-month period.

*Incidental registration rights.* If we register any of our common stock, either for our own account or for the account of other security holders, subject to certain exceptions, these stockholders are entitled to notice of the registration and to include their shares of common stock in the registration.

*Limitations and expenses.* With specified exceptions, a holder's right to include shares in a registration is subject to the right of the underwriters to limit the number of shares included in the offering. We will pay all fees, costs and expenses of any demand or incidental registrations, and the holders of the securities being registered will pay all selling expenses.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is

#### **NASDAQ National Market**

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

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#### **SHARES ELIGIBLE FOR FUTURE SALE**

Prior to this offering, there has been no market for our common stock, and we cannot assure you that a liquid trading market for our common stock will develop or be sustained after this offering. Future sales of substantial amounts of common stock, including shares issued upon exercise of options and warrants, in the public market after this offering, or the anticipation of those sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities.

Upon completion of this offering, we will have outstanding shares of common stock, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 11,730,012 shares of common stock.

Of the shares to be outstanding after completion of this offering, the shares sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining shares are "restricted securities" under Rule 144. Substantially all of these restricted securities will be subject to the 180-day lock-up period described below.

After the 180-day lock-up period, these restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act, which rules are summarized below.

#### **Rule 144**

In general, under Rule 144, beginning 90 days after the date of this prospectus, a person who has beneficially owned shares of our common stock for at least one year would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately shares immediately after this offering; and
- the average weekly trading volume of the common stock on the NASDAQ National Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. Upon completion of the 180-day lock-up period, substantially all of our outstanding restricted securities will be eligible for sale under Rule 144.

#### **Rule 144(k)**

Subject to the lock-up agreements described below, shares of our common stock eligible for sale under Rule 144(k) may be sold immediately upon the completion of this offering. In general, under Rule 144(k), a person may sell shares of common stock acquired from us immediately upon completion of this offering, without regard to manner of sale, the availability of public information or volume, if:

- the person is not our affiliate and has not been our affiliate at any time during the three months preceding such a sale; and
- the person has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate.

Upon expiration of the 180-day lock-up period, unless held by our affiliates, 2,676,638 shares of common stock underlying our Series A convertible preferred stock, Series A prime convertible preferred stock and Series A double prime convertible preferred stock will be eligible for sale under Rule 144(k). In addition, unless held by our affiliates, 6,440,678 shares of common stock underlying our

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Series B convertible preferred stock will be eligible for sale under Rule 144(k) in May 2005. In addition, unless held by our affiliates, 2,612,696 shares of common stock underlying our Series C convertible preferred stock will be eligible for sale under Rule 144(k) in February 2006. Furthermore, unless held by our affiliates, the shares issued upon cashless exercise of the warrant to purchase Series A double prime convertible preferred stock will be eligible for sale under Rule 144(k) in December 2004.

#### **Rule 701**

In general, under Rule 701 of the Securities Act, any of our employees, consultants or advisors who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement are eligible to resell those shares 90 days after the effective date of this offering in reliance on Rule 144, but without compliance with various restrictions, including the holding period, contained in Rule 144. Subject to the 180-day lock-up period, approximately 797,605 shares of common stock will be eligible for sale in accordance with Rule 701.

#### **Lock-Up Agreements**

The holders of substantially all of our currently outstanding stock have agreed that, subject to the exceptions described in the "Underwriters" section, without the prior written consent of SG Cowen Securities Corporation and Banc of America Securities LLC on behalf of the underwriters, they will not, during the period ending 180 days after the date of this prospectus sell, offer, contract or grant any option to sell (including, without limitation any short sale), pledge, transfer, establish an open "put equivalent position" or otherwise dispose of any shares of our common stock, options or warrants to acquire shares of our common stock or securities exchangeable or exercisable for or convertible into shares of our common stock.

Furthermore, stockholders who purchased shares from us upon exercise of stock options have agreed with us that they will not sell any of their shares for a period of 180 days after the date of this prospectus.

#### **Registration Rights**

Upon the completion of this offering, the holders of an aggregate of 14,532,246 shares of our common stock, including shares issuable upon exercise of our outstanding warrant, will have the right to require us to register these shares under the Securities Act under certain circumstances. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. For more information regarding these registration rights, see "Description of Capital Stock—Registration Rights."

#### **Stock Options**

As of March 1, 2004, we had outstanding options to purchase 797,605 shares of common stock. Following this offering, we intend to file registration statements on Form S-8 under the Securities Act to register all of the shares of common stock subject to outstanding stock options together with options and other awards issuable pursuant to our 2002 stock incentive plan, 2004 stock incentive plan and 2004 employee stock purchase plan.

### Warrants

Upon completion of this offering, there will be a warrant outstanding to purchase 12,500 shares of our common stock at an exercise price of \$2.87 per share. Any shares purchased pursuant to the "cashless exercise" feature of this warrant will be freely tradeable under Rule 144(k).

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## UNDERWRITING

### General

Under the underwriting agreement, which is filed as an exhibit to the registration statement relating to this prospectus, each of the underwriters named below has severally agreed to purchase from us the number of shares of common stock shown opposite its name below:

Underwriters	Number of Shares
SG Cowen Securities Corporation	
Banc of America Securities LLC	
CIBC World Markets Corp.	
ThinkEquity Partners LLC	
Total	

The underwriting agreement provides that the underwriters' obligations to purchase shares of common stock depend on the satisfaction of the conditions contained in the underwriting agreement, including:

- the obligation to purchase all of the shares of common stock offered hereby if any of the shares are purchased;
- the representations and warranties made by us to the underwriters are true;
- there is no material change in the financial markets; and
- we deliver customary closing documents to the underwriters.

SG Cowen Securities Corporation and Banc of America Securities LLC are acting as Joint Book-Running Managers on behalf of the underwriting syndicate. As Joint Book-Running Managers, they will be responsible for recording a list of potential investors that have expressed an interest in purchasing shares of common stock as part of this offering.

The underwriters have informed us that they do not expect to make sales to accounts over which they exercise discretionary authority to exceed five percent of the total number of shares of common stock offered by them.

### Over-Allotment Option

We have granted to the underwriters an option to purchase up to an aggregate of \_\_\_\_\_ additional shares of common stock, exercisable to cover over-allotments at the public offering price less the underwriting discount shown on the cover page of this prospectus. The underwriters may exercise this option at any time, and from time to time, until 30 days after the date of the underwriting agreement. To the extent the underwriters exercise this option, each underwriter will be committed, so long as the conditions of the underwriting agreement are satisfied, to purchase a number of additional shares of common stock proportionate to that underwriter's initial commitment as indicated in the preceding table, and we will be obligated to sell the additional shares of common stock to the underwriters.

### Commissions and Expenses

The following table summarizes the underwriting discount that we will pay. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an

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additional \_\_\_\_\_ shares from us. The underwriting fee is the difference between the public offering price and the amount the underwriters pay to purchase the shares from us.

	Paid by Momenta	
	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

The underwriters have advised us that they propose to offer the shares of common stock directly to the public at the public offering price

presented on the cover page of this prospectus, and to selected dealers, who may include the underwriters, at the public offering price less a selling concession not in excess of \$ \_\_\_\_\_ per share. The underwriters may allow, and the selected dealers may reallow, a concession not in excess of \$ \_\_\_\_\_ per share to brokers and dealers. After the offering, the underwriters may change the offering price and other selling terms.

We estimate that our total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts, will be approximately \$ \_\_\_\_\_.

#### **Lock-up Agreements**

We, our officers and directors and stockholders owning an aggregate of approximately 14,607,718 shares of common stock have entered into lock-up agreements with the underwriters. Under these agreements, we and each of these persons may not, without the prior written approval of SG Cowen Securities Corporation and Banc of America Securities LLC, offer, sell, contract to sell or otherwise dispose of or hedge our common stock or securities convertible into or exchangeable for our common stock. These restrictions will be in effect for a period of 180 days after the date of this prospectus. At any time and without notice, SG Cowen Securities Corporation and Banc of America Securities LLC may, in their sole discretion, release all or some of the securities from these lock-up agreements.

#### **Quotation on the NASDAQ National Market**

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

#### **Indemnification**

We have agreed to indemnify the underwriters against liabilities relating to the offering, including liabilities under the Securities Act and liabilities arising from breaches of the representations and warranties contained in the underwriting agreement, and to contribute to payments that the underwriters may be required to make for these liabilities.

#### **Stabilization, Short Positions and Penalty Bids**

The underwriters may engage in over-allotment, stabilizing transactions, syndicate covering transactions, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock, in accordance with Regulation M under the Securities Exchange Act:

- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the

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number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.

- Stabilizing transactions permit bids to purchase common stock so long as the stabilizing bids do not exceed a specified maximum.
- Syndicate covering transactions involve purchases of common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. If the underwriters sell more shares than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may raise or maintain the market price of our common stock or prevent or slow a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the NASDAQ National Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

#### **Passive Market Making**

In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on the NASDAQ National Market in accordance with Rule 103 of Regulation M under the Securities Exchange Act during the period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bids at a price not in excess of the highest independent bid of the security. However, if all independent bids are lowered below the passive market maker's bid, that bid must be lowered when specified purchase limits are exceeded.

#### **Prospectus Delivery**

Neither the underwriters nor any of their affiliates intend to use any means of distributing a prospectus other than by delivering a paper-based

copy of such prospectus by hand or postal mail.

### **Directed Share Program**

At our request, the underwriters have reserved for sale, at the initial public offering price, up to \_\_\_\_\_ shares offered in this prospectus for directors, officers, employees, business associates and other persons with whom we have a relationship. The number of shares of common stock available for sale to the general public will be reduced to the extent these persons purchase reserved shares. Any

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reserved shares which are not purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.

### **Pricing of the Offering**

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives. Among the factors to be considered in determining the initial public offering price will be our future prospects and those of our industry in general, our revenues, earnings and other financial operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities and financial and operating information of companies engaged in activities similar to ours. The estimated initial public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors.

### **Conflicts/Affiliates**

The underwriters and their affiliates may from time to time engage in future transactions with us and our affiliates and provide services to us and our affiliates in the ordinary course of their business for which services they may in the future receive customary fees.

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### **LEGAL MATTERS**

Certain legal matters with respect to the validity of the shares of common stock offered hereby will be passed upon for us by Hale and Dorr LLP, Boston, Massachusetts. Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

### **EXPERTS**

Ernst & Young LLP, independent auditors, have audited our financial statements at December 31, 2002 and 2003, and the period from May 17, 2001 (date of our inception) to December 31, 2001 and the years ended December 31, 2002 and 2003, as set forth in their report. We have included our financial statements in the prospectus in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

### **WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document. When we complete this offering, we will also be required to file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. We anticipate making these documents publicly available, free of charge, on our website at [www.momentapharma.com](http://www.momentapharma.com) as soon as reasonably practicable after filing such documents with the Securities and Exchange Commission.

You can read the registration statement and our future filings with the Securities and Exchange Commission, over the Internet at the Securities and Exchange Commission's web site at <http://www.sec.gov>. You may also read and copy any document that we file with the Securities and Exchange Commission at its public reference room at 450 Fifth Street, N.W., Washington, DC 20549.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the Securities and Exchange Commission at 450 Fifth Street, NW, Washington, DC 20549. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the operation of the public reference room.

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**MOMENTA PHARMACEUTICALS, INC.**

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## REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Stockholders  
Momenta Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Momenta Pharmaceuticals, Inc. as of December 31, 2002 and 2003, and the related statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the period from May 17, 2001 (date of inception) to December 31, 2001 and the years ended December 31, 2002 and 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Momenta Pharmaceuticals, Inc. at December 31, 2002 and 2003, and the results of its operations and its cash flows for the period from May 17, 2001 (date of inception) to December 31, 2001 and the years ended December 31, 2002 and 2003, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 17 to the financial statements, the Company restated certain amounts previously reported as of and for the year ended December 31, 2002.

/s/ ERNST & YOUNG LLP

Boston, Massachusetts  
February 27, 2004, except for Note 16, as to  
which the date is March 8, 2004

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## MOMENTA PHARMACEUTICALS, INC.

### BALANCE SHEETS

	December 31,		Unaudited Pro Forma December 31, 2003
	2002	2003	
	Restated		(Note 2)
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 1,470,554	\$ 4,612,674	\$ 25,012,674
Short-term investments	—	7,994,250	7,994,250
Unbilled collaboration revenue	—	2,018,380	2,018,380
Prepaid expenses and other current assets	53,136	261,551	261,551
Total current assets	1,523,690	14,886,855	35,286,855
Property and equipment, net of accumulated depreciation	867,829	1,117,206	1,117,206
Other assets	108,586	79,520	79,520

Total assets	\$ 2,500,105	\$ 16,083,581	\$ 36,483,581
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit</b>			
Current liabilities:			
Accounts payable	\$ 287,515	\$ 804,137	\$ 804,137
Accrued expenses	603,639	570,867	570,867
Deferred revenue	—	147,155	147,155
Line of credit obligation	—	320,868	320,868
Total current liabilities	891,154	1,843,027	1,843,027
Deferred revenue—net of current portion	—	416,938	416,938
Line of credit obligation—net of current portion	—	371,614	371,614
Unvested restricted stock	12,888	6,476	6,476
Total liabilities	904,042	2,638,055	2,638,055
Commitments and contingencies			
Redeemable convertible preferred stock, \$0.01 par value, issuable in series; 10,000,000 shares authorized at December 31, 2002 and 2003 and 12,000,000 authorized pro forma; 2,676,638, 9,117,316 and 11,730,012 shares issued and outstanding at December 31, 2002, 2003 and pro forma, respectively; aggregate liquidation preference of \$25,175,000 and \$45,675,000 at December 31, 2003 and pro forma, respectively	6,426,628	27,224,586	47,624,586
Stockholders' deficit:			
Common stock, \$0.0001 par value; 12,000,000, 20,000,000 and 30,000,000 shares authorized at December 31, 2002, 2003 and pro forma, respectively; 3,250,487, 3,252,193 and 3,252,193 shares issued and outstanding at December 31, 2002, 2003 and pro forma, respectively	325	325	325
Additional paid-in-capital	2,809,679	4,960,561	25,339,592
Accumulated other comprehensive loss	—	(5,996)	(5,996)
Due from officer	(106,584)	(71,056)	(71,056)
Deferred compensation	(1,748,918)	(3,034,312)	(3,034,312)
Accumulated deficit	(5,785,067)	(15,628,582)	(36,007,613)
Total stockholders' deficit	(4,830,565)	(13,779,060)	(13,779,060)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 2,500,105	\$ 16,083,581	\$ 36,483,581

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**MOMENTA PHARMACEUTICALS, INC.**

**STATEMENTS OF OPERATIONS**

	Period from Date of Inception (May 17, 2001) through December 31, 2001	Years ended December 31,	
		2002	2003
Collaboration revenue	\$ —	\$ —	\$ 1,454,287
Operating expenses:			
Research and development*	206,437	2,173,639	5,347,845
General and administrative*	166,824	2,711,989	4,082,880

Restated

Total operating expenses		373,261	4,885,628	9,430,725
Loss from operations		(373,261)	(4,885,628)	(7,976,438)
Interest income		2,228	16,965	73,969
Interest expense		—	—	(42,920)
Net loss		(371,033)	(4,868,663)	(7,945,389)
Dividends and accretion to redemption value of redeemable convertible preferred stock		(21,917)	(520,359)	(1,898,126)
Net loss attributable to common stockholders	\$	(392,950)	\$ (5,389,022)	\$ (9,843,515)
Basic and diluted net loss attributable to common stockholders per common share	\$	(8.63)	\$ (7.29)	\$ (6.42)
Shares used in computing basic and diluted net loss attributable to common stockholders per common share		45,532	739,073	1,532,251
Unaudited pro forma basic and diluted net loss attributable to common stockholders per common share				\$ (0.95)
Shares used in computing unaudited pro forma basic and diluted net loss attributable to common stockholders per common share				8,373,272

\*Includes stock-based compensation of the following:

Research and development	\$	—	\$ 47,710	\$ 173,102
General and administrative		—	348,272	682,576
Total stock-based compensation	\$	—	\$ 395,982	\$ 855,678

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**MOMENTA PHARMACEUTICALS, INC.**

**STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK  
AND STOCKHOLDERS' EQUITY (DEFICIT)**

Period from Inception (May 17, 2001) through December 31, 2003

	Redeemable Convertible Preferred Stock		Common Stock			Accumulated Other Comprehensive Loss	Due from Officer	Deferred Stock Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Par Value	Additional Paid-in Capital					
Issuance of common stock to founders			2,093,752	\$ 209						\$ 209
Sale of Series A Redeemable Convertible Preferred Stock, net of offering costs of \$20,880 and value ascribed to warrants of \$232,215	250,000				\$ 232,215			\$ (3,095)		229,120
Issuance of common stock to nonemployees			154,194	16	15,403					15,419
Accretion of Preferred Stock to redemption value		\$ 12,533						(12,533)		(12,533)
Preferred Stock dividends		9,384						(9,384)		(9,384)
Net loss								(371,033)		(371,033)



Repurchase of invested restricted stock	(16,544)	(2)								(2)
Vesting of restricted stock			4,757							4,757
Unrealized loss on short-term investments				\$	(5,996)					(5,996)
Net loss								(7,945,389)		(7,945,389)
Comprehensive loss										(7,951,385)
Balances at December 31, 2003	9,117,316	\$ 27,224,586	3,252,193	\$ 325	\$ 4,960,561	\$ (5,996)	\$ (71,056)	\$ (3,034,312)	\$ (15,628,582)	\$ (13,779,060)

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**MOMENTA PHARMACEUTICALS INC.**

**STATEMENTS OF CASH FLOWS**

	Period from Date of Inception (May 17, 2001) through December 31, 2001	Years ended December 31,	
		2002	2003
		Restated	
<b>Operating activities:</b>			
Net loss	\$ (371,033)	\$ (4,868,663)	\$ (7,945,389)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation	438	84,320	252,497
Stock compensation expense	15,420	395,982	855,678
Noncash license expense	—	278,932	—
Noncash interest expense	—	—	9,128
Changes in operating assets and liabilities:			
Unbilled collaboration revenue	—	—	(2,018,380)
Prepaid expenses and other current assets	(718)	(22,543)	(238,290)
Other assets	—	(108,586)	29,066
Accounts payable	33,334	254,181	516,622
Accrued expenses	277,012	326,627	(32,772)
Deferred revenue	—	—	564,093
Net cash used in operating activities	(45,547)	(3,659,750)	(8,007,747)
<b>Investing activities</b>			
Purchases of property and equipment	(2,627)	(949,960)	(501,875)
Purchases of marketable securities	—	—	(8,001,902)
Net cash used in investing activities	(2,627)	(949,960)	(8,503,777)
<b>Financing activities</b>			
Proceeds from issuance of redeemable convertible preferred stock, net of cash paid for issuance costs	229,120	5,884,352	18,899,832
Proceeds from line of credit	—	—	1,002,278
Payments on line of credit	—	—	(289,049)
Payment of officer obligation	—	—	35,528
Proceeds from issuance of common stock	209	14,757	5,055
Net cash provided by financing activities	229,329	5,899,109	19,653,644
Net increase in cash and cash equivalents	181,155	1,289,399	3,142,120
Cash and cash equivalents at beginning of period	—	181,155	1,470,554
Cash and cash equivalents at end of period	\$ 181,155	\$ 1,470,554	\$ 4,612,674

Supplemental disclosure of cash flow information:

Interest paid	—	—	\$	33,792
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**MOMENTA PHARMACEUTICALS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**1. The Company**

Momenta Pharmaceuticals, Inc. (the "Company" or "Momenta") was incorporated in the state of Delaware on May 17, 2001. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the 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.

Momenta is subject to risks common to companies in the biotechnology industry including, but not limited to, uncertainty of product development and commercialization, lack of marketing and sales history, dependence on key personnel, market acceptance of products, product liability, protection of proprietary technology, ability to raise additional financing and compliance with FDA and other government regulations.

Prior to 2003, the Company did not generate any revenue and operated as a development-stage company for financial statement reporting purposes. Effective 2003, the Company ceased to be considered a development-stage company for financial statement reporting purposes as a result of the collaboration agreement with the Sandoz N.V. and Sandoz Inc., each an affiliate of Novartis AG ("Sandoz") (see Note 3).

**2. Summary of Significant Accounting Policies**

***Use of Estimates***

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

***Cash, Cash Equivalents, and Short-Term Investments***

The Company invests its excess cash in bank deposits, money market accounts, corporate debt securities, and U.S. government obligations. The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and primarily consist of money market funds maintained at major U.S. financial institutions.

All short-term investments, which primarily represent marketable debt securities, have been classified as "available-for-sale." Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive loss and reported as a separate component of stockholders' deficit. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest earned on short-term investments is included in interest income.

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***Credit Risks and Concentrations***

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

***Fair Value of Financial Instruments***

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

***Property and Equipment***

Property and equipment is stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets which range from three to seven years. Leasehold improvements are amortized over the estimated useful lives of the assets or related lease terms, whichever is shorter.

***Long-Lived Assets***

The Company evaluates the recoverability of its property and equipment and other long-lived assets when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of Statement of Financial Account Standards ("SFAS") No. 144, *Accounting for the Impairment of Disposal of Long-Lived Assets* (SFAS No. 144). SFAS No. 144 further refines the requirements of SFAS No. 121, *Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of*, that companies (1) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (2) measure an impairment loss as the difference between the carrying amount and fair value of the asset. Impairment is measured based on the difference

between the carrying value of the related assets or businesses and the undiscounted future cash flows of such assets or businesses. In addition, SFAS No. 144 provides guidance on accounting and disclosure issues surrounding long-lived assets to be disposed of by sale. No impairment charges have been required to be recognized through December 31, 2003.

### Revenue Recognition

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

The Company uses revenue recognition criteria outlined in Staff Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements*, as revised by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force ("EITF") Issue 00-21 *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Accordingly, revenues from licensing agreements are recognized based on the

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performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are generally recorded as deferred revenue in the balance sheet and amortized into collaboration revenue in the statement of operations over the term of the performance obligation. Revenues from research and development services and expenses are recognized in the period the services are performed and the reimbursable costs are incurred.

### Research and Development

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

### Stock-Based Compensation

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

Pro forma information regarding net loss is required by SFAS 123 as if the Company had accounted for its stock-based awards to employees under the fair value method of SFAS 123. The fair value of the Company's stock options used to compute pro forma net loss is the estimated value at the grant date using the Black-Scholes option-pricing model with the following weighted-average assumptions for the period from inception (May 17, 2001) through December 31, 2001 (Fiscal 2001) and the fiscal years ended December 31, 2002 and 2003 (Fiscal 2002 and 2003, respectively):

	2001	2002	2003
Risk-free interest rate	4.6%	4.5%	3.5%
Expected volatility	80%	80%	80%
Expected lives	7 years	7 years	7 years
Expected dividend	—	—	—

The per-share, weighted-average grant date fair value of options granted during Fiscal 2001, 2002 and 2003 were \$0.08, \$1.86 and \$4.52, respectively.

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

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plans consistent with the method of SFAS 123, the Company's net loss for fiscal 2001, 2002 and 2003 would have been as follows:

	2001	2002	2003
Net loss attributable to common stockholders as reported	\$ (392,950)	\$ (5,389,022)	\$ (9,843,515)
Add: Stock-based employee compensation expense included in reported net loss	—	52,452	280,460
Deduct: Stock-based employee compensation expense determined under fair value based method	(13)	(34,687)	(280,090)
SFAS 123 Pro forma net loss	\$ (392,963)	\$ (5,371,257)	\$ (9,843,145)
Basic and diluted net loss per share			
As reported	\$ (8.63)	\$ (7.29)	\$ (6.42)

SFAS 123 Pro forma	\$	(8.63)	\$	(7.27)	\$	(6.42)
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### **Redeemable Convertible Preferred Stock**

The carrying value of redeemable convertible preferred stock will be increased by periodic accretions so that the carrying amount will equal the redemption value at the redemption date. These accretions will be effected through charges against accumulated deficit. As discussed in Note 7, the holders of Series A, Series A Prime, Series A Double Prime and Series B Redeemable Convertible Preferred Stock are entitled to dividends at 10% per annum through each redemption date, payable only upon redemption.

### **Income Taxes**

The Company accounts for income taxes under SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered.

### **Comprehensive Loss**

The Company reports comprehensive loss in accordance with SFAS No. 130, *Reporting Comprehensive Income* (SFAS 130). SFAS 130 establishes rules for the reporting and display of comprehensive loss and its components. Accumulated other comprehensive loss as of December 31, 2003 consists entirely of unrealized losses on available-for-sale securities. Comprehensive loss for Fiscal 2001 and 2002 equaled net loss.

### **Net Loss Per Share**

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings per Share* (SFAS No. 128). Under the provisions of SFAS 128, basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding. Diluted net loss per

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common share is computed by dividing net loss by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Common equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock, shares issuable upon the exercise of stock options and the conversion of preferred stock upon the exercise of warrants. The Company has excluded the impact of all convertible preferred stock, stock options and shares of common stock subject to repurchase from the calculation of historical diluted net loss per common share because all such securities are antidilutive for all periods presented. The total number of shares excluded from the calculations of historical diluted net loss per share was 2,096,966, 5,173,591 and 11,196,886 for Fiscal 2001, 2002 and 2003, respectively.

### **Unaudited Pro Forma Net Loss Per Share**

Unaudited pro forma net loss per share is computed using the weighted average number of common shares outstanding, including the pro forma effects of the automatic conversion of all redeemable convertible preferred stock outstanding as of December 31, 2003, into shares of the Company's common stock effective upon the assumed closing of the Company's proposed initial public offering, as if such conversion had occurred at the date of the original issuance.

### **Unaudited Pro Forma Balance Sheet Presentation**

The unaudited pro forma balance sheet as of December 31, 2003 reflects the sale of 2,612,696 shares of Series C Redeemable Convertible Preferred Stock on February 27, 2004 for net proceeds of \$20.4 million and the beneficial conversion feature, valued at approximately \$20.4 million, related to the Series C shares sold in February 2004 at less than deemed fair value.

### **Segment Reporting**

The Company has adopted SFAS No. 131, *Disclosure About Segments of an Enterprise and Related Information*, which requires companies to report selected information about operating segments, as well as enterprisewide disclosures about products, services, geographical areas, and major customers. Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance. The Company has only one operating segment, the discovery, development and commercialization of drug products.

### **Recently Issued Accounting Standards**

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 the Company does not currently have any unconsolidated variable interest entities, the Company does not expect the adoption of FIN 46 to have a material impact on its financial position or results of operations.

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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. The Company does not expect the adoption of this statement will have a material impact on its financial statements.

### 3. Collaboration and License Agreements

#### *Sandoz*

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

Under this collaboration, Sandoz will pay us for scientific, technical and/or management services. Sandoz is also responsible for funding substantially all of the other ongoing development and commercialization costs and legal expenses incurred with respect to M-Enoxaparin, subject to an agreed-upon limit. As of December 31, 2003, we have recorded unbilled collaboration revenue of \$2.0 million, including \$0.6 million for an initial payment (for reimbursement of development costs we incurred prior to signing the agreement) and \$1.4 million for personnel and other reimburseable development costs. The unbilled receivable of \$2.0 million was subsequently billed and is due in the first quarter of 2004. The initial payment was deferred and is being amortized into revenue over the development period, estimated to be four years. Of this amount, \$24,526 was recorded as revenue in 2003. The personnel and other reimbursable costs were recorded as revenue in 2003. Upon commercialization, Sandoz will share profits with us or pay royalties to us on net sales of M-Enoxaparin in the United States. Sandoz may also make additional payments to us up to an aggregate of \$55.0 million, upon our achievement of a specific regulatory milestone and a series of annual commercial milestones. If the development and commercialization costs and legal expenses, in the aggregate, exceed a specified amount, Sandoz is permitted to offset a portion of the excess against the profit-sharing amounts, the royalties and the commercial milestone payments.

We have granted Sandoz the right to negotiate additional rights under certain circumstances, including an exclusive license to develop and commercialize M-Enoxaparin outside of the United States.

#### *Massachusetts Institute of Technology*

In December 2001, we entered into an exclusive patent license agreement with the Massachusetts Institute of Technology ("M.I.T."), that was subsequently amended and restated in early November 2002 and further amended in 2003. We entered into an additional exclusive patent license agreement with M.I.T. in late October 2002. These two agreements grant us various exclusive and nonexclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to methods and technologies for analyzing and characterizing sugars and certain heparins, heparinases and other enzymes and synthesis methods. Subject to typical retained rights of M.I.T. and

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the United States government, we are granted exclusive rights under certain of these patents and applications in certain fields.

In exchange for these rights, we paid M.I.T. a license issue fee and we pay annual license maintenance fees. We are also required to pay M.I.T. royalties on products and services covered by the licenses and sold by us or our affiliates or sublicensees, a percentage of certain other income received by us from corporate partners and sublicensees, and certain patent prosecution and maintenance costs. M.I.T. and certain contributing individuals were also issued shares of our common stock. We made payments of \$0.3 million to M.I.T. in Fiscal 2002 and 2003.

Pursuant to the license agreement, the Company issued an aggregate of 154,194 shares of common stock to M.I.T. and certain of its affiliates (the "University Stockholders"). In connection with the issuance of common stock, the Company recorded \$15,420 in research and development expense during 2001 representing the fair market value of the common stock at the time of issuance. Subject to certain conditions, the University Stockholders were entitled to additional shares of common stock, such that the University Stockholders' ownership of the Company's outstanding common stock, in the aggregate, would not be less than 5% on a fully-diluted basis. Such additional shares were to be issued on the date upon which the Company received a total of \$5.0 million in cash in exchange for the Company's capital stock. On April 16, 2002, the Company reached such \$5.0 million equity threshold and distributed an aggregate of 138,772 additional shares of common stock to the University Stockholders. Upon such distribution, all rights to further issuances were terminated. In connection with the issuance of common stock, the Company recorded \$278,932 in research and development expense during Fiscal 2002 representing the fair market value of the common stock at the time of issuance.

If, due to our failure to meet diligence obligations, M.I.T. converts certain of our exclusive licenses to non-exclusive, or if M.I.T. terminates one of the agreements, M.I.T. will honor the exclusive nature of the sublicense we granted to Sandoz so long as Sandoz both continues to fulfill its obligations to us under the collaboration and license agreement and agrees to assume our rights and obligations to M.I.T.

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

In November 2002, we entered into an agreement with The Regents of the University of California through the Ernest Orlando Lawrence Berkeley National Laboratory ("Lawrence Berkeley National Lab") under which we licensed certain patents and applications covering the metabolic synthesis of sugars and glycoconjugates and were granted an exclusive license, with the right to grant sublicenses, for the synthesis, production or modification of sugars and glycoconjugates in or on biological molecules for purposes of researching, developing and commercializing products, services and processes for all human therapeutic applications, excluding the sale of research reagents.

After November 20, 2004, we may retain the license under this broad field if we have met certain diligence obligations and pay a fee. If we do not do so, the field narrows to three therapeutic applications that we select from an agreed upon list, each to be more thoroughly defined through negotiation.

In return for these license rights, we paid Lawrence Berkeley National Lab a license issue fee, and we must pay royalties, subject to annual minimum amounts. If we sublicense our rights, we also pay a

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percentage of the fees received from our sublicensees. We are also responsible for patent prosecution and maintenance costs. We made payments to Lawrence Berkeley National Lab in Fiscal 2002 and 2003 of \$20,000 and \$59,352, respectively.

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

In October 2003, we entered into a process development and production agreement with Siegfried (U.S.A), Inc. and Siegfried Ltd. ("Siegfried") under which we provide to Siegfried our existing laboratory-scale processes and analytical methods for the production of enoxaparin. Siegfried's responsibility is to further develop the processes and, once we approve of such processes, manufacture the active pharmaceutical ingredient enoxaparin sodium for use in stability, preclinical, and clinical studies and for other development purposes. We paid Siegfried \$0.2 million for services in Fiscal 2003.

#### 4. Financial Instruments

The following is a summary of cash, cash equivalents, and short-term investments as of December 31, 2002 and 2003:

December 31, 2002	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash	\$ 1,470,554	\$ —	\$ —	\$ 1,470,554
Reported as:				
Cash and cash equivalents	\$ 1,470,554	\$ —	\$ —	\$ 1,470,554
December 31, 2003	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash	\$ 261,126	\$ —	\$ —	\$ 261,126
Money market funds	1,846,025	—	—	1,846,025
Corporate debt securities	10,505,769	—	(5,996)	10,499,773
	\$ 12,612,920	\$ —	\$ (5,996)	\$ 12,606,924
Reported as:				
Cash and cash equivalents	\$ 4,614,179	\$ —	\$ (1,505)	\$ 4,612,674
Short-term investments	7,998,741	—	(4,491)	7,994,250
	\$ 12,612,920	\$ —	\$ (5,996)	\$ 12,606,924

At December 31, 2003, all short-term investments have remaining contractual maturities of less than twelve months, there were no gross unrealized gains and the unrealized losses are not believed to be other-than-temporary.

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#### 5. Property and Equipment

At December 31, 2002 and 2003, property and equipment, net consists of the following:

	2002	2003
Computer equipment	\$ 113,821	\$ 140,306
Office furniture and equipment	8,397	14,219
Laboratory equipment	695,844	1,082,526
Leasehold improvements	134,525	217,411
Less: accumulated depreciation	(84,758)	(337,256)
	\$ 867,829	\$ 1,117,206

Depreciation expense amounted to \$438, \$84,320 and \$252,497 for Fiscal 2001, 2002 and 2003, respectively.

#### 6. Accrued Expenses

At December 31, 2002 and 2003, accrued expenses consisted of the following:

	2002	2003
Accrued compensation	\$ 226,462	\$ 209,742

Accrued contracted research costs	6,925	102,630
Accrued license fees	214,808	59,051
Accrued professional fees	147,781	90,560
Other	7,663	108,884
	\$ 603,639	\$ 570,867

## 7. Redeemable Convertible Preferred Stock and Stockholders' Equity

Redeemable convertible preferred stock is summarized below:

	Shares Designated	Shares Issued and Outstanding	Per Share Liquidation Preference	Aggregate Liquidation Preference
Series A	250,000	250,000	\$ 1.00	\$ 250,000
Series A Prime	893,537	893,537	1.7067	1,525,000
Series A Double Prime	1,545,601	1,533,101	2.87	4,400,000
Series B	6,440,678	6,440,678	2.95	19,000,000
	9,129,816	9,117,316		\$ 25,175,000

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At December 31, 2002 and 2003, the carrying value of redeemable convertible preferred stock, reflecting dividends and accretion to redemption value, is summarized below:

	2002	2003
Series A	\$ 80,721	\$ 139,525
Series A Prime	1,650,524	1,806,281
Series A Double Prime	4,695,383	5,138,766
Series B	—	20,140,014
	\$ 6,426,628	\$ 27,224,586

### Dividends

The holders of Series A Redeemable Convertible Preferred Stock (Series A Preferred), Series A Prime Redeemable Convertible Preferred Stock (Series A Prime Preferred), Series A Double Prime Redeemable Convertible Preferred Stock (Series A Double Prime Preferred) and Series B Redeemable Convertible Preferred Stock (Series B Preferred), collectively the Preferred Stock, are entitled to receive dividends equal to any dividend paid on the Company's Common Stock. The holders of the Preferred Stock are entitled to dividends at 10% per annum through each redemption date, payable only upon redemption.

### Liquidation Preference

In the event of a liquidation, either voluntary or involuntary, dissolution or winding up of the affairs of the Company, the holders of Preferred Stock are entitled to receive their stated per share liquidation preference value, adjusted for any stock splits or dividends, combinations or other recapitalizations affecting such series, plus all declared but unpaid dividends before any payment is made to the holders of Common Stock. If the assets of the Company are insufficient to pay the full preferential amount to holders of each of the series of Preferred Stock, the assets are distributed ratably among the holders of Preferred Stock in proportion to the full preferential amount each holder is otherwise entitled to receive. After full payment has been made to the holders of all series of Preferred Stock, all remaining assets are distributed to holders of Common Stock.

### Conversion

Each share of Preferred Stock is convertible at any time into that number of shares of Common Stock that results from dividing \$1.00, \$1.7067, \$2.87 and \$2.95 for the Series A Preferred, the Series A Prime Preferred, the Series A Double Prime Preferred and the Series B Preferred, respectively, by the then-applicable conversion price for each series of Preferred Stock in effect at the time of conversion, adjustable for certain dilutive events. The applicable conversion price as of December 31, 2003 was \$1.00, \$1.7067, \$2.87 and \$2.95 for the Series A Preferred, the Series A Prime Preferred, the Series A Double Prime Preferred and the Series B Preferred, respectively. Each share of Preferred Stock automatically converts, at the conversion rate described above, upon an initial public offering resulting in gross proceeds to the Company of at least \$15,000,000 at a per share price to the public of at least \$10.00 per share. Notwithstanding the foregoing, in the event that (i) the pricing committee of the board of directors approves a per share price in connection with a firm commitment underwritten offering at less than \$10.00 per share, (ii) 66<sup>2</sup>/<sub>3</sub>% of the shares of Preferred Stock approve such

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adjusted price and (iii) the adjusted price is no less than \$7.8463, each share of Preferred Stock shall automatically convert into shares of common stock.

Each share of Series A Preferred, Series A Prime Preferred, Series A Double Prime Preferred and Series B Preferred automatically converts upon the written consent of 66<sup>2</sup>/<sub>3</sub>% or more of the shares of such Preferred Stock outstanding at that time. Each share of Series C Preferred automatically converts upon the written consent of 66<sup>2</sup>/<sub>3</sub>% or more of the shares of such Preferred Stock outstanding at that time.

#### *Voting Rights*

Each holder of Preferred Stock is entitled to the number of votes equal to the number of whole shares of Common Stock into which the shares of the particular series of Preferred Stock are convertible.

#### *Redemption*

Upon the demand of a majority of shares of a series of Preferred Stock, each stockholder of such series has the right to require redemption of such preferred stockholder's shares. If the funds of the Company are insufficient to redeem the total number of shares on any date, the holders of such shares share ratably in any funds available for redemption based on the respective amounts that they would have been entitled to receive.

Each holder of the respective series of the Preferred Stock has the right to cause the Company, on May 9, 2008, May 9, 2009 and May 9, 2010 to redeem, on a cumulative basis, from each such holder of shares at the redemption price of each respective series, 33<sup>1</sup>/<sub>3</sub>%, 66<sup>2</sup>/<sub>3</sub>% and 100%, respectively, of the outstanding shares of the various Preferred Stock. The redemption price is equal to the price originally paid per share for each respective series of Preferred Stock plus dividends of 10% per annum through the redemption date. The Company is accreting dividends for the Preferred Stock to their respective redemption values assuming redemption occurs at the earliest date permitted.

### **8. Warrants**

On August 16, 2001, in connection with the Series A Preferred offering, the Company issued warrants (the Series A Prime Preferred Warrants) to purchase an aggregate of 585,926 shares of Series A Prime Preferred at an exercise price of \$1.7067 per share.

The fair market value (\$232,215) of the Series A Prime Preferred Warrants on their issuance date was recorded as a reduction in the carrying amount of the Series A Preferred. This reduction will be accreted to retained earnings ratably over the period from the warrant issuance through the Series A Preferred redemption dates. The fair value was estimated using the Black-Scholes model with the following assumptions: 0.00% dividend yield, 80% volatility, 4.49% risk-free interest rate and an expected term of 0.44 years. These warrants were exercised or terminated in 2002.

In 2002, in connection with a bank line of credit agreement, the Company granted a warrant to purchase 12,500 shares of Series A Double Prime Redeemable Convertible Preferred Stock at an exercise price of \$2.87 per share. This warrant was immediately exercisable and expires in December 2012. The fair value of the warrant was estimated to be \$29,875, which was recorded as additional paid-in capital and as prepaid interest at December 31, 2002. This prepaid interest amount is

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being amortized as interest expense over the 36-month term of the line of credit. The fair value was estimated using the Black-Scholes model with the following assumptions: 0% dividend yield, 80% volatility, 3.92% risk-free interest rate and an expected term of ten years (equal to the life of the warrant).

### **9. Common Stock**

Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company.

At December 31, 2002 and 2003, shares of common stock reserved for future issuance are as follows:

	2002	2003
Common stock:		
Conversion of convertible preferred stock	2,676,638	9,117,316
Exercise of outstanding options and warrant	350,702	817,730
Shares available for grant under stock option plans	687,527	194,730
	3,714,867	10,129,776

#### *Share Restriction Agreements*

On June 13, 2001, the Company entered into Restricted Stock Purchase Agreements with certain employees and nonemployees to purchase an aggregate of 2,093,752 shares of common stock. Each Restricted Stock Purchase Agreement provides for the repurchase of common stock held by these individuals and entities by the Company at a rate of \$0.0001 per share, the original purchase price, adjustable for certain dilutive events, until the shares vest. The repurchase provisions lapse over a 45-month period commencing on September 13, 2001, provided that each individual and entity subject to such agreements continues service with the Company.

During 2002, the Company entered into Restricted Stock Purchase Agreements with two officers and a nonemployee to purchase an aggregate of 860,836 shares of common stock. Pursuant to one of the Restricted Stock Purchase Agreements, 766,296 shares of common stock were sold to an officer for \$106,662. The purchase price is payable ratably over approximately three years and is included in stockholders' deficit as Due from Officer. Each Restricted Stock Purchase Agreement provides for the repurchase of common stock held by these individuals and entities by the Company at a price equal to the original price paid, adjustable for certain dilutive events, until the shares vest. The repurchase provisions generally lapse over a three-to four-year period provided that each individual and entity subject to such agreements continues service with the Company.

At December 31, 2002 and 2003, there were 2,158,751 and 1,274,340 shares of unvested restricted common stock outstanding, respectively. The weighted-average fair value of restricted stock granted during fiscal 2001 and 2002 was \$0.0001 and \$2.01 per share, respectively.

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## 10. Stock Option Plan

The Company's 2002 Stock Incentive Plan, as amended, provides for the granting of stock options and restricted stock to employees, officers, directors, consultants and advisors to purchase the Company's Common Stock. As of December 31, 2003, the Company was authorized to issue options to purchase 1,028,662 shares of Common Stock under the 2002 Stock Incentive Plan. Options granted under the 2002 Stock Incentive Plan may be Incentive Stock Options or Nonstatutory Stock Options under the applicable provisions of the Internal Revenue Code.

Incentive Stock Options are granted only to employees of the Company. Incentive Stock Options granted to employees who own more than 10% of the total combined voting power of all classes of stock will be granted at no less than 110% of the fair market value of the Company's common stock on the date of grant. Nonstatutory Stock Options may be granted to employees, officers, directors, consultants and advisors. Incentive Stock Options generally vest either upon grant or ratably over four years. Nonstatutory Stock Options granted have varying vesting schedules. The options generally expire ten years after the date of grant.

The following table summarizes all stock plan activity:

	Stock Options		
	Shares Outstanding	Price Per Share	Weighted-Average Exercise Price
Shares granted	14,933	\$0.10	\$ 0.10
Balance at December 31, 2001	14,933	0.10	0.10
Shares granted	366,202	0.29	0.29
Shares exercised	(2,933)	0.10	0.10
Shares canceled	(40,000)	0.29	0.29
Balance at December 31, 2002	338,202	0.10-0.29	0.28
Shares granted	485,278	0.29-0.77	0.43
Shares exercised	(18,250)	0.10-0.29	0.28
Balance at December 31, 2003	805,230	\$0.10-0.77	\$ 0.37

The following table summarizes information about options outstanding at December 31, 2003:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (In years)	Number of Shares	Weighted Average Exercise Price
\$0.10	10,750	\$ 0.10	8.0	4,003	\$ 0.10
0.29-0.295	656,980	0.29	9.1	95,316	0.29
0.77	137,500	0.77	9.8	—	0.77
	805,230	\$ 0.37	9.2	99,319	\$ 0.28

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## Stock-Based Compensation

As discussed in Note 1, the Company applies APB 25 and related interpretations in accounting for stock options granted under the 2002 Plan. In Fiscal 2002 and 2003, the Company recorded \$0.5 million and \$2.0 million, respectively, in deferred compensation for employee stock options granted at exercise prices deemed to be below the fair value of common stock. In addition, in Fiscal 2002 the Company recorded \$1.6 million in deferred compensation for restricted stock granted to employees at purchase prices deemed to be below the fair value of common stock.

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

As of December 31, 2003, the Company expects to record stock-based compensation expense of approximately \$1.0 million, \$1.0 million,

and \$0.7 million in the years ending December 31, 2004, 2005, and 2006, respectively, related to currently outstanding employee stock options and restricted stock.

### Stock Options to Consultants

As of December 31, 2003, the Company had granted options to purchase 49,532 shares of common stock to consultants, 5,000 of which were exercised, none of which were subject to repurchase, and 30,658 of which were unvested. These options were granted in exchange for consulting services to be rendered and vest over periods of up to four years. The Company recorded charges to operations for stock options granted to consultants using the graded-vesting method of \$15,420, \$36,385, \$184,400 for Fiscal 2001, 2002 and 2003, respectively.

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

### 11. Income Taxes

A reconciliation of federal statutory income tax provision to the Company's actual provision for Fiscal 2001, 2002 and 2003 is as follows:

	2001	2002	2003
Benefit at federal statutory tax rate	\$ (126,151)	\$ (1,568,530)	\$ (2,701,432)
Unbenefited operating losses	126,151	1,559,015	2,668,472
Other	—	9,515	32,960
Income tax provision	\$ —	\$ —	\$ —

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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2002	2003
<b>Deferred tax assets:</b>		
Federal and state net operating losses	\$ 1,804,294	\$ 4,430,567
Research credits	99,286	253,599
Deferred compensation	168,962	525,625
Deferred revenue	—	227,160
Total deferred tax assets	\$ 2,072,542	\$ 5,436,951
<b>Deferred tax liabilities:</b>		
Depreciation	(31,430)	(58,281)
Total deferred tax liabilities	(31,430)	(58,281)
Valuation allowance	(2,041,112)	(5,378,670)
Net deferred tax assets	\$ —	\$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by \$1.8 million and \$3.3 million for Fiscal 2002 and 2003, respectively.

As of December 31, 2003, the Company had net operating loss carryforwards of \$11.0 million to offset future federal and state taxable income. The Company also has federal and state research and development tax credits of approximately \$178,000 and \$115,000, respectively, as of December 31, 2003. The net operating loss carryforwards and federal research credits expire at various times through 2023.

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

### 12. Net Loss and Unaudited Pro forma Net Loss Per Share

The following table sets forth the computation of basic and diluted, and unaudited pro forma basic and diluted, net loss per share for Fiscal 2001, 2002 and 2003. The unaudited pro forma basic and

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diluted net loss per share gives effect to the assumed conversion of the redeemable convertible preferred stock and the accrued dividends as if converted at the date of original issuance.

	2001	2002	2003
<i>Basic and diluted:</i>			
Net loss	\$ (371,033)	\$ (4,868,663)	\$ (7,945,389)
Dividends and accretion to redemption value of redeemable convertible preferred stock	(21,917)	(520,359)	(1,898,126)
Net loss attributable to common stockholders	\$ (392,950)	\$ (5,389,022)	\$ (9,843,515)
Shares used in computing basic and diluted net loss attributable to common stockholders per common share	45,532	739,073	1,532,251
Basic and diluted net loss attributable to common stockholders per common share	\$ (8.63)	\$ (7.29)	\$ (6.42)
<i>Unaudited pro forma basic and diluted:</i>			
Net loss			\$ (7,945,389)
Shares used in computing basic and diluted net loss attributable to common stockholders per share			1,532,251
Weighted average number of common shares assuming the conversion of all redeemable convertible preferred stock at the original date of issuance			6,841,021
Weighted average common shares used to compute unaudited pro forma net loss per share			8,373,272
Unaudited pro forma basic and diluted net loss per share			\$ (0.95)

### 13. Commitments and Contingencies

The Company leases office space and equipment under various operating lease agreements. Rent expense under operating leases amounted to \$0, \$217,126 and \$329,195 in Fiscal 2001, 2002 and 2003, respectively.

Future minimum payments under noncancelable leases with terms of one year or more are as follows:

2004	\$ 342,021
2005	3,135
2006	2,835
2007	473
Total minimum lease payments	\$ 348,464

We are engaged in discussions with a third party regarding the lease of new office and laboratory space which, if entered into, would significantly increase our annual lease commitments over the next

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five years. Because we have not yet reached a definitive agreement, we are not currently able to estimate the expected increase.

In connection with license arrangements signed during 2001 and 2002 with the research universities discussed in Note 3, the Company has certain annual fixed obligations to pay these institutions fees for the technology licensed. Financial obligations under these agreements are as follows:

2004	\$ 67,500
2005	102,500
2006	102,500
2007	102,500
2008	127,500

After 2008, the annual obligations, which extend indefinitely, range from \$182,000 to \$217,500 per year. The Company may terminate the agreements at any time without obligation for future payments. Annual payments may be applied towards royalties payable to the licensors for that year for product sales, sublicensing of the patent rights or joint development revenue.

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

the future. The accompanying financials do not include any provision or reserves for such potential litigation.

#### **14. Line of Credit**

In December 2002, the Company entered into an equipment line of credit with Silicon Valley Bank, which provided for the Company to draw up to \$1.2 million through March 31, 2003. Borrowings under the line bear interest at a rate between 5.0% and Prime plus 0.25% and are payable over a 36-month period from the cash drawn date. The line of credit includes a provision that any material adverse change in the Company or its business may be considered an event of default. There have been no events of default. As of December 31, 2003, the Company had drawn \$1.0 million against the line of credit.

#### **15. 401(k) Plan**

In 2003, the Company established a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company has discretion to make contributions to the plan; however, to date no contributions have been made.

#### **16. Subsequent Events**

##### *Series C Issuance*

On February 27, 2004, the Company issued 2,612,696 shares of Series C Redeemable Convertible Preferred Stock, \$0.01 par value per share, at a per share price of \$7.8463, resulting in net proceeds to

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the Company of \$20.4 million. These shares carry the same terms and conditions as disclosed in Note 7, and automatically convert to Common Stock upon the closing of an underwritten public offering of Common Stock. These shares contain a beneficial conversion feature based on the fair value of the Common Stock upon conversion. In accordance with EITF 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, the value of such beneficial conversion feature, approximately \$20.4 million, will be recognized as a dividend in the first quarter of 2004.

##### *Registration Statement*

On March 8, 2004, the Company's Board of Directors authorized the filing of a registration statement with the Securities and Exchange Commission in connection with the Company's proposed initial public offering. If the offering is completed upon the terms presently contemplated, all outstanding shares of convertible preferred stock will automatically convert into 11,730,012 shares of common stock upon completion of the proposed offering.

##### *2004 Stock Incentive Plan*

The Company's 2004 Stock Incentive Plan (the Incentive Plan) was adopted by the Company's board of directors on March 8, 2004, subject to approval by the Company's stockholders. The Incentive Plan will become effective on the date that the registration statement, of which this prospectus forms a part, is declared effective. The Incentive Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. The total shares issuable under the Incentive Plan will be determined prior to the effective date of the Company's registration statement described above.

##### *2004 Employee Stock Purchase Plan*

The Company's 2004 Employee Stock Purchase Plan (the Purchase Plan) was adopted by the Company's board of directors on March 8, 2004, subject to approval by the Company's stockholders. The Purchase Plan will become effective on the date that the registration statement, of which this prospectus forms a part, is declared effective. The Purchase Plan will allow employees to purchase stock at a price equal to 85% of the lower of the closing price of the Common Stock on the first day or the last day of each six-month offering period. The total shares issuable under the Purchase Plan will be determined prior to the effective date of the Company's registration statement described above.

#### **17. Restatement of 2002 Financial Statements**

As discussed in Notes 9 and 10, the Company granted or issued a substantial number of shares of common stock and common stock options during the fiscal year ended December 31, 2002 at exercise prices that were considered to approximate the fair market value of such equity securities at that time. Upon further consideration, the Company has determined that such valuations may not have adequately reflected external equity market conditions and has restated the December 31, 2002 financial statements to reflect fair values for the Company's common stock that are materially higher and consistent with those values used for the 2003 financial statements. The revisions to the fair values of common stock resulted in increases of \$22,899 in research and development expense and \$348,274 in general and administrative expense for grants to employees and consultants, and an increase of

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\$278,932 in research and development expense for equity consideration in connection with a license agreement. The Company also properly recognized a license fee which increased research and development expense by \$54,059, for an aggregate increase in research and development expense of \$355,890. In addition, the Company decreased interest income by \$93. Accordingly, the Company increased the originally reported net loss and net loss attributable to common stockholders per common share for 2002 from \$4,164,406 to \$4,868,663 and from \$6.34 per share to \$7.29 per share, respectively.

#### **18. Selected Quarterly Financial Data (Unaudited)**

Quarter Ended

	March 31	June 30	September 30	December 31
<b>2002 (Restated)</b>				
Net loss	\$ (277,047)	\$ (1,250,937)	\$ (1,495,537)	\$ (1,845,142)
Net loss attributable to common stockholders	(320,859)	(1,398,656)	(1,659,952)	(2,009,555)
Basic and diluted net loss per common share	\$ (0.73)	\$ (2.06)	\$ (1.96)	\$ (2.05)
Weighted average common shares used to compute net loss per share	442,086	679,127	846,321	981,651
<b>2003</b>				
Collaborative revenues	—	—	—	\$ 1,454,287
Net loss	\$ (1,497,563)	\$ (1,801,414)	\$ (2,380,309)	\$ (2,266,103)
Net loss attributable to common stockholders	(1,662,049)	(2,143,069)	(3,076,301)	(2,962,096)
Basic and diluted net loss per common share	(1.44)	(1.46)	(1.86)	(1.61)
Weighted average common shares used to compute net loss per share	1,151,759	1,469,605	1,653,880	1,844,808

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

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

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Shares



SG Cowen

Banc of America Securities LLC

CIBC World Markets

ThinkEquity Partners

Prospectus

, 2004

Through and including , 2004 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee and the National Association of Securities Dealers Inc. filing fee.

Securities and Exchange Commission registration fee	\$ 10,927.88
National Association of Securities Dealers Inc. fee	9,125
NASDAQ Stock Market listing fee	5,000
Accountants' fees and expenses	350,000
Legal fees and expenses	*
Blue Sky fees and expenses	*
Transfer Agent's fees and expenses	*

Printing and engraving expenses		*
Miscellaneous		*
Total	\$	*

\* To be filed by amendment.

#### Item 14. Indemnification of Directors and Officers.

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our certificate of incorporation provides that no director shall be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

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Our certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, our director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

#### Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of common stock and preferred stock issued, and options and warrants granted, by the Registrant within the past three years. Also included is the consideration, if any, received by the Registrant for such shares, options and warrants and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Issuances of Capital Stock.

- (1) In June 2001, in connection with the Registrant's formation, the Registrant issued and sold an aggregate of 2,093,752 shares of its restricted common stock at a price per share of \$0.0001. These purchasers consisted of Robert S. Langer, Jr., Ram Sasisekharan, Ganesh Venkataraman, Alan L. Crane, Peter Barton Hutt, Lansing Brown Investments, LLC and Paul Schimmel.
- (2) In January 2002, the Registrant issued and sold 24,063 shares of its restricted common stock at a price per share of \$0.10 to Chi-Huey Wong. In August 2003, the Registrant repurchased 16,544 of these shares at a price per share of \$0.10. In March 2002, the Registrant issued and sold 766,296 shares of its restricted common stock at a price per share of \$0.0001 to Alan L. Crane. In April 2002, the Registrant issued and sold 70,477 shares of its restricted common stock at a price per share of

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- (3) In August 2001, the Registrant issued and sold an aggregate of 250,000 shares of its Series A convertible preferred stock at a price per share of \$1.00, together with warrants to purchase an aggregate of 585,926 shares of its Series A prime convertible preferred stock with an exercise price per share of \$1.7067. Upon the closing of this offering, these shares will convert into 250,000 shares of common stock. These investors consisted of Polaris Venture Partners III, L.P., Polaris Venture Partners Entrepreneurs' Fund III, L.P., Polaris Venture Partners Founders' Fund III, L.P. and Robert M. Metcalfe. In January 2002, the warrant issued to Robert M. Metcalfe to purchase 46,874 shares of Series A prime convertible preferred stock was terminated.
  - (4) In January 2002, the Registrant issued and sold an aggregate of 893,537 shares of its Series A prime convertible preferred stock at a price of \$1.7067. Of these 893,537 shares of Series A prime convertible preferred stock, 539,052 shares were issued pursuant to the exercise of warrants issued to Polaris Venture Partners III, L.P., Polaris Venture Partners Entrepreneurs' Fund III, L.P., Polaris Venture Partners Founders' Fund III, L.P. in August 2001, at a price per share of \$1.7067. Upon the closing of this offering, these shares will convert into 893,537 shares of common stock. These investors consisted of Polaris Venture Partners III, L.P., Polaris Venture Partners Entrepreneurs' Fund III, L.P., Polaris Venture Partners Founders' Fund III, L.P., Lansing Brown Investments, LLC, Alan L. Crane, Robert S. Langer, Jr., Peter Barton Hutt, Susan K. Whoriskey, BQ Ventures, LLC, The Paul Schimmel PS Plan and Wolf, Greenfield & Sacks Investment Trust, LLC.
  - (5) In April 2002, the Registrant issued and sold an aggregate of 1,533,101 shares of its Series A double prime convertible preferred stock at a price per share of \$2.87. Upon the closing of this offering, these shares will convert into 1,533,101 shares of common stock. These investors consisted of Polaris Venture Partners III, L.P., Polaris Venture Partners Entrepreneurs' Fund III, L.P., Polaris Venture Partners Founders' Fund III, L.P., CHP II, L.P., Lansing Brown Investments, LLC and James R. and Mary W. McNab Operating L.P.
  - (6) In May 2003, the Registrant issued and sold an aggregate of 6,440,678 shares of its Series B convertible preferred stock at a price per share of \$2.95. Upon the closing of this offering, these shares will convert into 6,440,678 shares of common stock. These investors consisted of Atlas Venture Fund V, L.P., Atlas Venture Parallel Fund, V-A, C.V., Atlas Venture Parallel Fund V-B, C.V., Atlas Venture Entrepreneurs' Fund V, L.P., Atlas Venture Fund VI, L.P., Atlas Venture Entrepreneurs' Fund VI, L.P., Atlas Venture Fund VI GmbH & Co. KG, MVM International Life Sciences Fund No. 1 L.P., MVM Limited, Stephen T. Reeders, David Brister, Paul Triniman, Polaris Venture Partners III, L.P., Polaris Venture Partners Entrepreneurs' Fund III, L.P., Polaris Venture Partners Founders' Fund, III, L.P. and CHP II, L.P.
  - (7) In February 2004, the Registrant issued and sold an aggregate of 2,612,696 shares of its Series C convertible preferred stock at a price per share of \$7.8463. Upon the closing of this offering, these shares will convert into 2,612,696 shares of common stock. These investors consisted of Mithra Ventures, L.P., Atlas Venture Fund V, L.P., Atlas Venture Parallel Fund, V-A, C.V., Atlas Venture Parallel Fund V-B, C.V., Atlas Venture Entrepreneurs' Fund V, L.P., Atlas Venture Fund VI, L.P., Atlas Venture Entrepreneurs' Fund VI, L.P., Atlas Venture Fund VI GmbH & Co. KG, MVM International Life Sciences Fund No. 1 L.P., MVM Limited, Stephen T. Reeders, David Brister, Paul Triniman, Martin Murphy, Richard Lim, Thomas Casdagli, Polaris Venture Partners III, L.P., Polaris Venture Partners Entrepreneurs' Fund III, L.P., Polaris Venture Partners Founders' Fund, III, L.P. and CHP II, L.P.

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- (8) In December 2001 and April 2002, the Registrant issued an aggregate of 292,966 shares of its common stock to the Massachusetts Institute of Technology and certain individuals affiliated with the Massachusetts Institute of Technology in connection with a certain license agreement.
  - (9) In December 2002, the Registrant issued a warrant to purchase an aggregate of 12,500 shares of its Series A double prime convertible preferred stock with an exercise price per share of \$2.87 to Silicon Valley Bank.

No underwriters were involved in the foregoing sales of securities. We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (a)(1) through (a)(5), (a)(8) and (a)(9) above by virtue of Section 4(2) of the Securities Act in that such sales and issuances did not involve a public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (a)(6) and (a)(7) by virtue of Section 4(2) of the Securities Act and Rule 506 of Regulation D. Such sales and issuances did not involve any public offering, were made without general solicitation or advertising and each purchaser was a sophisticated investor with access to all relevant information necessary to evaluate the investment and represented to us that the shares were being acquired for investment.

(b) Stock Option Grants.

As of March 1, 2004, the Registrant had granted stock options under its stock incentive plan for an aggregate of 797,605 shares of common stock (net of exercises, expirations and cancellations) at a weighted average exercise price of \$0.38 per share. Options to purchase 43,058 shares of common stock have been exercised for an aggregate purchase price of \$11,692.05.

The issuance of stock options and the common stock issuable upon the exercise of such options as described in this paragraph (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with our employees, directors and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of common stock described in this Item 15 included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits

Exhibit No.	Description
1.1*	Underwriting Agreement
3.1**	Second Amended and Restated Certificate of Incorporation
3.2**	Amended and Restated By-laws
3.3**	Form of Third Amended and Restated Certificate of Incorporation to be effective upon the closing of the offering
3.4**	Form of Second Amended and Restated By-laws to be effective upon the closing of the offering

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4.1*	Specimen Certificate evidencing shares of common stock
4.2**	Warrant to Purchase Stock, dated December 27, 2002, issued to Silicon Valley Bank; Acknowledgement and Agreement, dated February 25, 2004, by Silicon Valley Bancshares
4.3**	Second Amended and Restated Investors' Rights Agreement, dated February 27, 2004, by and among the Purchasers listed therein, the Founders listed therein and the Registrant
5.1*	Opinion of Hale and Dorr LLP
10.1**	Amended and Restated 2002 Stock Incentive Plan
10.2	2004 Stock Incentive Plan
10.3	2004 Employee Stock Purchase Plan
10.4†**	Collaboration and License Agreement, dated November 1, 2003, by and among Biochemie West Indies, N.V., Geneva Pharmaceuticals, Inc. and the Registrant (this agreement is referred to in this Registration Statement as the collaboration and license agreement with Sandoz)
10.5†**	Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Registrant (the "November 1, 2002 M.I.T. License"); First Amendment to the November 1, 2002 M.I.T. License, dated November 15, 2002, by and between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated September 12, 2003, between the Massachusetts Institute of Technology and the Registrant; Letter Agreement, dated October 22, 2003, between the Massachusetts Institute of Technology and the Registrant; Second Amendment to the November 1, 2002 M.I.T. License, dated November 19, 2003, by and between the Massachusetts Institute of Technology and the Registrant
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10.9**	Employment Agreement, dated March 15, 2002, by and between Alan L. Crane and the Registrant
10.10**	Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Alan L. Crane and the Registrant
10.11**	Restricted Stock Purchase Agreement, dated March 15, 2002, by and between Alan L. Crane and the Registrant
10.12**	First Amended and Restated Employment Agreement, dated April 10, 2002, by and between Ganesh Venkataraman and the Registrant
10.13**	Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Ganesh Venkataraman and the Registrant
10.14**	Reallocation of Founder Shares Agreement, dated April 10, 2002, by and among Ganesh Venkataraman, Ram Sasisekharan, Robert S. Langer, Jr., Polaris Venture Partners III, L.P. and the Registrant
10.15**	Employment Agreement, dated April 10, 2002, by and between Susan Whoriskey and the Registrant

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10.16**	Restricted Stock Purchase Agreement, dated April 10, 2002, by and between Susan Whoriskey and the Registrant
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- 10.17\*\* Consulting Agreement, dated July 23, 2001, by and between Robert S. Langer, Jr. and the Registrant; Letter of Extension dated June 23, 2003
- 10.18\*\* Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Robert S. Langer, Jr. and the Registrant
- 10.19\*\* Consulting Agreement, dated August 16, 2001, by and between Ram Sasisekharan and the Registrant; Letter of Extension dated August 1, 2003
- 10.20\*\* Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Ram Sasisekharan and the Registrant
- 10.21\*\* Consulting Agreement, dated September 18, 2002, by and between Peter Barton Hutt and the Registrant; Letter of Extension dated September 29, 2003
- 10.22\*\* Restricted Stock Purchase Agreement, dated June 13, 2001, by and between Peter Barton Hutt and the Registrant
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- 10.24\*\* Sublease, dated February 25, 2002, by and between Curis, Inc. and the Registrant
- 10.25\*\* Commercial Lease Agreement (68 Moulton Street—3rd Floor), dated October 16, 2003, by and between 68 Moulton Street Realty Trust and the Registrant; Extension of Lease dated February 11, 2004
- 10.26\*\* Commercial Lease Agreement (68 Moulton Street—2nd Floor), dated February 1, 2004, by and between 68 Moulton Street Realty Trust and the Registrant
- 21.1\*\* Subsidiaries of the Registrant
- 23.1 Consent of Ernst & Young LLP
- 23.2\* Consent of Hale and Dorr LLP (included in Exhibit 5.1)
- 24.1\*\* Power of Attorney (see page II-9)

\* To be filed by amendment.

\*\* Previously filed.

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

(b) Financial Statement Schedules.

None

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#### Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective.
- (2) For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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#### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 1 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts on this 16th day of April, 2004.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ ALAN L. CRANE

Alan L. Crane  
Chairman, President and Chief Executive Officer

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**SIGNATURES AND POWER OF ATTORNEY**

Pursuant to the requirements of the Securities Act of 1933, this Amendment No. 1 to Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ALAN L. CRANE	Chairman, President, Chief Executive Officer and Director (Principal Executive Officer)	April 16, 2004
Alan L. Crane		
/s/ RICHARD P. SHEA	Chief Financial Officer (Principal Financial and Accounting Officer)	April 16, 2004
Richard P. Shea		
*		
Peter Barrett, Ph.D.	Director	April 16, 2004
*		
John K. Clarke	Director	April 16, 2004
*		
Peter Barton Hutt, LL.B., LL.M.	Director	April 16, 2004
*		
Robert S. Langer, Jr., Sc.D.	Director	April 16, 2004
*		
Stephen T. Reeders, D.M., MRCP	Director	April 16, 2004
*		
Ram Sasisekharan, Ph.D.	Director	April 16, 2004
*		
Bennett M. Shapiro, M.D.	Director	April 16, 2004
*		
Christoph H. Westphal, M.D., Ph.D.	Director	April 16, 2004
*		
John L. Zabriskie, Ph.D.	Director	April 16, 2004

By the signature set forth below, the undersigned, pursuant to the duly authorized powers of attorney filed with the Securities and Exchange Commission, has signed this Amendment No. 1 to Registration Statement on behalf of the person indicated.

\* By: /s/ ALAN L. CRANE

Alan L. Crane  
Attorney-in-Fact

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## EXHIBIT INDEX

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\* To be filed by amendment.

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

## MOMENTA PHARMACEUTICALS, INC.

## 2004 STOCK INCENTIVE PLAN

## 1. PURPOSE

The purpose of this 2004 Stock Incentive Plan (the "Plan") of Momenta Pharmaceuticals, Inc., a Delaware corporation (the "Company"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align their interests with those of the Company's stockholders. Except where the context otherwise requires, the term "Company" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "Board").

## 2. ELIGIBILITY

All of the Company's employees, officers, directors, consultants and advisors are eligible to receive options, restricted stock awards, stock appreciation rights and other stock-based awards (each, an "Award") under the Plan. Each person who receives an Award under the Plan is deemed a "Participant".

## 3. ADMINISTRATION AND DELEGATION

(a) ADMINISTRATION BY BOARD OF DIRECTORS. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under the Plan made in good faith.

(b) APPOINTMENT OF COMMITTEES. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "Committee"). All references in the Plan to the "Board" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers.

(c) DELEGATION TO OFFICERS. To the extent permitted by applicable law, the Board may delegate to one or more officers of the Company the power to grant Awards to employees or

officers of the Company or any of its present or future subsidiary corporations and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of the Awards to be granted by such officers (including the exercise price of such Awards, which may include a formula by which the exercise price will be determined) and the maximum number of shares subject to Awards that the officers may grant; provided further, however, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) or to any "officer" of the Company (as defined by Rule 16a-1 under the Exchange Act).

## 4. STOCK AVAILABLE FOR AWARDS

(a) NUMBER OF SHARES. Subject to adjustment under Section 10, Awards may

be made under the Plan for up to the number of shares of the Company's common stock, par value \$0.0001 per share (the "Common Stock"), that is equal to the sum of:

- (1) 3,084,988 shares of Common Stock; plus
- (2) an annual increase to be added on the first day of each of the Company's fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013 equal to the lowest of (i) 1,542,494 shares of Common Stock, (ii) 5% of the outstanding shares on such date and (iii) an amount determined by the Board.

Notwithstanding clause (2) above, in no event shall the number of shares available under this Plan be increased as set forth in clause (2) to the extent such increase, in addition to any other increases proposed by the Board in the number of shares available for issuance under all other employee or director stock plans, including, without limitation, employee stock purchase plans, would result in the total number of shares then available for issuance under all employee and director stock plans exceeding 25% of the outstanding shares of the Company on the first day of the applicable fiscal year.

If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan, subject, however, in the case of Incentive Stock Options, to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(b) PER-PARTICIPANT LIMIT. Subject to adjustment under Section 10, for Awards granted after the Common Stock is registered under the Exchange Act, the maximum number of shares of Common Stock with respect to which Awards may be granted to any Participant under the Plan shall be 400,000 per calendar year. The per-Participant limit described in this Section 4(b) shall be construed and applied consistently with Section 162(m) of the Code ("Section 162(m)").

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## 5. STOCK OPTIONS

(a) GENERAL. The Board may grant options to purchase Common Stock (each, an "Option") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable. An Option which is not intended to be an Incentive Stock Option (as hereinafter defined) shall be designated a "Nonstatutory Stock Option".

(b) INCENTIVE STOCK OPTIONS. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "Incentive Stock Option") shall only be granted to employees of Momenta Pharmaceuticals, Inc., any of Momenta Pharmaceutical Inc.'s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. The Company shall have no liability to a Participant, or any other party, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or for any action taken by the Board pursuant to Section 11(f), including without limitation the conversion of an Incentive Stock Option to a Nonstatutory Stock Option.

(c) EXERCISE PRICE. The Board shall establish the exercise price of each Option and specify such exercise price in the applicable option agreement.

(d) DURATION OF OPTIONS. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement; provided, however, that no Option will be granted for a term in excess of 10 years.

(e) EXERCISE OF OPTION. Options may be exercised by delivery to the

Company of a written notice of exercise signed by the proper person or by any other form of notice (including electronic notice) approved by the Board together with payment in full as specified in Section 5(f) for the number of shares for which the Option is exercised.

(f) PAYMENT UPON EXERCISE. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

- (1) in cash or by check, payable to the order of the Company;
- (2) except as the Board may otherwise provide in an option agreement, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;
- (3) when the Common Stock is registered under the Exchange Act, by delivery of shares of Common Stock owned by the Participant valued at their fair market value as determined by (or in a manner approved by) the Board ("Fair Market Value"), provided (i) such method of payment

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is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant at least six months prior to such delivery and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent permitted by applicable law and by the Board, by (i) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (ii) payment of such other lawful consideration as the Board may determine; or

(5) by any combination of the above permitted forms of payment.

(g) SUBSTITUTE OPTIONS. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Options in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Options may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Options contained in the other sections of this Section 5 or in Section 2.

## 6. DIRECTOR OPTIONS.

(a) INITIAL GRANT. Upon the commencement of service on the Board by any individual who is not then an employee of the Company or any subsidiary of the Company, the Company shall grant to such person a Nonstatutory Stock Option to purchase no more than 30,000 shares of Common Stock (subject to adjustment under Section 10).

(b) ANNUAL GRANT. Subject to an annual evaluation, which evaluation shall be overseen by the Corporation's Nominating and Corporate Governance Committee, on the date of each annual meeting of stockholders of the Company, the Company shall grant to each member of the Board of Directors of the Company who is both serving as a director of the Company immediately prior to and immediately following such annual meeting and who is not then an employee of the Company or any of its subsidiaries, a Nonstatutory Stock Option to purchase no more than 15,000 shares of Common Stock (subject to adjustment under Section 10); provided, however, that a director shall not be eligible to receive an option grant under this Section 6(b) until such director has served on the Board for at least six months.

(c) TERMS OF DIRECTOR OPTIONS. Options granted under this Section 6 shall (i) have an exercise price equal to the last reported sale price of the Common Stock on The Nasdaq Stock Market or the national securities exchange on which the Common Stock is then traded on the trading date immediately prior to the date of grant (and if the Common Stock is not then traded on The Nasdaq Stock Market or a national securities exchange, the fair market value of the Common Stock on such date as determined by the Board), (ii) expire on the earlier of 10 years from the date of grant or three months following termination of service on the Board and (iii) contain such other terms and

conditions as the Board shall determine.

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7. STOCK APPRECIATION RIGHTS.

(a) NATURE OF STOCK APPRECIATION RIGHTS. A Stock Appreciation Right, or SAR, is an Award entitling the holder on exercise to receive an amount in cash or Common Stock or a combination thereof (such form to be determined by the Board) determined in whole or in part by reference to appreciation, from and after the date of grant, in the fair market value of a share of Common Stock. SARs may be based solely on appreciation in the fair market value of Common Stock or on a comparison of such appreciation with some other measure of market growth such as (but not limited to) appreciation in a recognized market index. The date as of which such appreciation or other measure is determined shall be the exercise date unless another date is specified by the Board in the SAR Award.

(b) GRANTS. Stock Appreciation Rights may be granted in tandem with, or independently of, Options granted under the Plan.

(1) RULES APPLICABLE TO TANDEM AWARDS. When Stock Appreciation Rights are expressly granted in tandem with Options, (i) the Stock Appreciation Right will be exercisable only at such time or times, and to the extent, that the related Option is exercisable and will be exercisable in accordance with the procedure required for exercise of the related Option; (ii) the Stock Appreciation Right will terminate and no longer be exercisable upon the termination or exercise of the related Option, except that a Stock Appreciation Right granted with respect to less than the full number of shares covered by an Option will not be reduced until the number of shares as to which the related Option has been exercised or has terminated exceeds the number of shares not covered by the Stock Appreciation Right; (iii) the Option will terminate and no longer be exercisable upon the exercise of the related Stock Appreciation Right; and (iv) the Stock Appreciation Right will be transferable only with the related Option.

(2) EXERCISE OF INDEPENDENT STOCK APPRECIATION RIGHTS. A Stock Appreciation Right not expressly granted in tandem with an Option will become exercisable at such time or times, and on such conditions, as the Board may specify in the SAR Award.

(c) EXERCISE. Any exercise of a Stock Appreciation Right must be in writing, signed by the proper person and delivered or mailed to the Company, accompanied by any other documents required by the Board.

8. RESTRICTED STOCK.

(a) GRANTS. The Board may grant Awards entitling recipients to acquire shares of Common Stock, subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award (each, a "Restricted Stock Award").

(b) TERMS AND CONDITIONS. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for repurchase (or forfeiture) and the issue price, if any.

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(c) STOCK CERTIFICATES. Any stock certificates issued in respect of a Restricted Stock Award shall be registered in the name of the Participant and, unless otherwise determined by the Board, deposited by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death (the "Designated Beneficiary"). In the absence of an effective designation by a Participant, "Designated Beneficiary" shall mean the Participant's estate.

(d) DEFERRED DELIVERY OF SHARES. The Board may, at the time any

Restricted Stock Award is granted, provide that, at the time Common Stock would otherwise be delivered pursuant to the Award, the Participant shall instead receive an instrument evidencing the right to future delivery of Common Stock at such time or times, and on such conditions, as the Board shall specify. The Board may at any time accelerate the time at which delivery of all or any part of the Common Stock shall take place.

9. OTHER STOCK-BASED AWARDS.

Other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property, may be granted hereunder to Participants ("Other Stock Unit Awards"), including without limitation Awards entitling recipients to receive shares of Common Stock to be delivered in the future. Such Other Stock Unit Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock Unit Awards may be paid in shares of Common Stock or cash, as the Board shall determine. Subject to the provisions of the Plan, the Board shall determine the conditions of each Other Stock Unit Awards, including any purchase price applicable thereto. At the time any Award is granted, the Board may provide that, at the time Common Stock would otherwise be delivered pursuant to the Award, the Participant will instead receive an instrument evidencing the Participant's right to future delivery of the Common Stock.

10. ADJUSTMENTS FOR CHANGES IN COMMON STOCK AND CERTAIN OTHER EVENTS.

(a) CHANGES IN CAPITALIZATION. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under this Plan, (ii) the per-Participant limit set forth in Section 4(b), (iii) the number and class of securities and exercise price per share of each outstanding Option and each Option issuable under Section 6, (iv) the repurchase price per share subject to each outstanding Restricted Stock Award and (v) the share- and per-share-related provisions of each outstanding Stock Appreciation Right and Other Stock Unit Award, shall be appropriately adjusted by the Company (or substituted Awards may be made, if applicable) to the extent determined by the Board.

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(b) REORGANIZATION EVENTS.

(1) DEFINITION. A "Reorganization Event" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged for the right to receive cash, securities or other property, (b) any exchange of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange transaction or (c) any liquidation or dissolution of the Company.

(2) CONSEQUENCES OF A REORGANIZATION EVENT ON AWARDS OTHER THAN RESTRICTED STOCK AWARDS. In connection with a Reorganization Event, the Board shall take any one or more of the following actions as to all or any outstanding Awards on such terms as the Board determines: (i) provide that Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that the Participant's unexercised Options or other unexercised Awards shall become exercisable in full and will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "Acquisition Price"), make or provide for a cash payment to a Participant equal to (A) the Acquisition Price times the number of shares of Common Stock subject to the Participant's Options or other Awards (to the extent the exercise price does not exceed the Acquisition Price) minus (B) the aggregate exercise price of all such outstanding Options or other Awards, in exchange for the termination of such Options or other Awards, (v) provide that,

in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise price thereof) and (vi) any combination of the foregoing.

For purposes of clause (i) above, an Option shall be considered assumed if, following consummation of the Reorganization Event, the Option confers the right to purchase, for each share of Common Stock subject to the Option immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Reorganization Event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Options to consist solely of common stock of the acquiring or succeeding corporation (or an affiliate thereof) equivalent in fair market value to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

To the extent all or any portion of an Option becomes exercisable solely as a result of clause (ii) above, the Board may provide that upon exercise of such Option the

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Participant shall receive shares subject to a right of repurchase by the Company or its successor at the Option exercise price; such repurchase right (x) shall lapse at the same rate as the Option would have become exercisable under its terms and (y) shall not apply to any shares subject to the Option that were exercisable under its terms without regard to clause (ii) above.

(3) CONSEQUENCES OF A REORGANIZATION EVENT ON RESTRICTED STOCK AWARDS. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company under each outstanding Restricted Stock Award shall inure to the benefit of the Company's successor and shall apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to the Common Stock subject to such Restricted Stock Award. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock Award or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock Awards then outstanding shall automatically be deemed terminated or satisfied.

#### 11. GENERAL PROVISIONS APPLICABLE TO AWARDS

(a) TRANSFERABILITY OF AWARDS. Except as the Board may otherwise determine or provide in an Award, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) DOCUMENTATION. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) BOARD DISCRETION. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) TERMINATION OF STATUS. The Board shall determine the effect on an Award of the disability, death, retirement, authorized leave of absence or other change in the employment or other status of a Participant and the extent to

which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.

(e) WITHHOLDING. Each Participant shall pay to the Company, or make provision satisfactory to the Company for payment of, any taxes required by law to be withheld in connection with an Award to such Participant. Except as the Board may otherwise provide in an Award, for so long as the Common Stock is registered under the Exchange Act, Participants may satisfy such tax obligations in whole or in part by delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value;

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provided, however, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income). Shares surrendered to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements. The Company may, to the extent permitted by law, deduct any such tax obligations from any payment of any kind otherwise due to a Participant.

(f) AMENDMENT OF AWARD. The Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option, provided that the Participant's consent to such action shall be required unless the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant.

(g) CONDITIONS ON DELIVERY OF STOCK. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(h) ACCELERATION. The Board may at any time provide that any Award shall become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

## 12. MISCELLANEOUS

(a) NO RIGHT TO EMPLOYMENT OR OTHER STATUS. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) NO RIGHTS AS STOCKHOLDER. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to such Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired

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upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(c) EFFECTIVE DATE AND TERM OF PLAN. The Plan shall become effective on the date on which it is adopted by the Board, but no Award may be granted unless and until the Plan has been approved by the Company's stockholders. No Awards shall be granted under the Plan after the completion of 10 years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date.

(d) AMENDMENT OF PLAN. The Board may amend, suspend or terminate the Plan or any portion thereof at any time; provided that, to the extent determined by the Board, no amendment requiring stockholder approval under any applicable legal, regulatory or listing requirement shall become effective until such stockholder approval is obtained. No Award shall be made that is conditioned upon stockholder approval of any amendment to the Plan.

(e) PROVISIONS FOR FOREIGN PARTICIPANTS. The Board may modify Awards or Options granted to Participants who are foreign nationals or employed outside the United States or establish subplans or procedures under the Plan to recognize differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters.

(f) GOVERNING LAW. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, without regard to any applicable conflicts of law.

MOMENTA PHARMACEUTICALS, INC.

2004 EMPLOYEE STOCK PURCHASE PLAN

The purpose of this Plan is to provide eligible employees of Momenta Pharmaceuticals, Inc. (the "Company") and certain of its subsidiaries with opportunities to purchase shares of the Company's common stock, par value \$0.0001 per share (the "Common Stock"), commencing on the date on which the Securities and Exchange Commission (the "SEC") declares a registration statement on Form S-1 for the initial public offering (the "IPO") of the Company's Common Stock effective (the "Effective Date"). An aggregate of 409,884 shares of Common Stock in the aggregate have been approved for this purpose. This Plan is intended to qualify as an "employee stock purchase plan" as defined in Section 423 of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations promulgated thereunder, and shall be interpreted consistent therewith.

1. ADMINISTRATION. The Plan will be administered by the Company's Board of Directors (the "Board") or by a Committee appointed by the Board (the "Committee"). The Board or the Committee has authority to make rules and regulations for the administration of the Plan and its interpretation and decisions with regard thereto shall be final and conclusive.

2. ELIGIBILITY. All employees of the Company, including Directors who are employees, and all employees of any subsidiary of the Company (as defined in Section 424(f) of the Code) designated by the Board or the Committee from time to time (a "Designated Subsidiary"), are eligible to participate in any one or more of the offerings of Options (as defined in Section 9) to purchase Common Stock under the Plan provided that:

(a) they are customarily employed by the Company or a Designated Subsidiary for more than 20 hours a week and for more than five (5) months in a calendar year; and

(b) they have been employed by the Company or a Designated Subsidiary for at least ninety (90) days prior to enrolling in the Plan; and

(c) they are employees of the Company or a Designated Subsidiary on the first day of the applicable Plan Period (as defined below).

No employee may be granted an option hereunder if such employee, immediately after the option is granted, owns 5% or more of the total combined voting power or value of the stock of the Company or any subsidiary. For purposes of the preceding sentence, the attribution rules of Section 424(d) of the Code shall apply in determining the stock ownership of an employee, and all stock which the employee has a contractual right to purchase shall be treated as stock owned by the employee.

3. OFFERINGS. The Company will make one or more offerings ("Offerings") to employees to purchase stock under this Plan. Offerings will begin each February 1, or the first business day thereafter (the "Offering Commencement Dates"). Each Offering Commencement Date will begin a twelve-month period (a "Plan Period") during which payroll deductions will be

made and held for the purchase of Common Stock at the end of the Plan Period. The Board or the Committee may, at its discretion, choose a different Plan Period of twelve (12) months or less for subsequent Offerings. Notwithstanding anything to the contrary, the first Plan Period shall begin on the first date that the Common Stock is publicly traded following the Company's IPO and shall end on January 31, 2005.

4. PARTICIPATION. An employee eligible on the Offering Commencement Date of any Offering may participate in such Offering by completing and forwarding a payroll deduction authorization form to the employee's appropriate payroll office at least ten (10) days prior to the applicable Offering Commencement Date. The form will authorize a regular payroll deduction from the Compensation received by the employee during the Plan Period. Unless an employee

files a new form or withdraws from the Plan, his deductions and purchases will continue at the same rate for future Offerings under the Plan as long as the Plan remains in effect. The term "Compensation" means the amount of money reportable on the employee's Federal Income Tax Withholding Statement, excluding overtime, shift premium, incentive or bonus awards, allowances and reimbursements for expenses such as relocation allowances for travel expenses, income or gains on the exercise of Company stock options or stock appreciation rights, and similar items, whether or not shown on the employee's Federal Income Tax Withholding Statement, but including, in the case of salespersons, sales commissions to the extent determined by the Board or the Committee.

5. DEDUCTIONS. The Company will maintain payroll deduction accounts for all participating employees. With respect to any Offering made under this Plan, an employee may authorize a payroll deduction in any dollar amount up to a maximum of 15% of the Compensation he or she receives during the Plan Period or such shorter period during which deductions from payroll are made. The minimum payroll deduction is such percentage of compensation as may be established from time to time by the Board or the Committee.

6. DEDUCTION CHANGES. An employee may decrease or discontinue his payroll deduction once during any Plan Period, by filing a new payroll deduction authorization form. However, an employee may not increase his payroll deduction during a Plan Period. If an employee elects to discontinue his payroll deductions during a Plan Period, but does not elect to withdraw his funds pursuant to Section 8 hereof, funds deducted prior to his election to discontinue will be applied to the purchase of Common Stock on the Exercise Date (as defined below).

7. INTEREST. Interest will not be paid on any employee accounts, except to the extent that the Board or the Committee, in its sole discretion, elects to credit employee accounts with interest at such per annum rate as it may from time to time determine.

8. WITHDRAWAL OF FUNDS. An employee may at any time prior to the close of business on the last business day in a Plan Period and for any reason permanently draw out the balance accumulated in the employee's account and thereby withdraw from participation in an Offering. Partial withdrawals are not permitted. The employee may not begin participation again during the remainder of the Plan Period. The employee may participate in any subsequent Offering in accordance with terms and conditions established by the Board or the Committee.

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9. PURCHASE OF SHARES. On the Offering Commencement Date of each Plan Period, the Company will grant to each eligible employee who is then a participant in the Plan an option ("Option") to purchase on the last business day of such Plan Period (the "Exercise Date"), at the Option Price hereinafter provided for, the largest number of whole shares of Common Stock of the Company as does not exceed the number of shares determined by multiplying \$2,083 by the number of full months in the Offering Period and dividing the result by the closing price (as defined below) on the Offering Commencement Date of such Plan Period.

Notwithstanding the above, no employee may be granted an Option (as defined in Section 9) which permits his rights to purchase Common Stock under this Plan and any other employee stock purchase plan (as defined in Section 423(b) of the Code) of the Company and its subsidiaries, to accrue at a rate which exceeds \$25,000 of the fair market value of such Common Stock (determined at the Offering Commencement Date of the Plan Period) for each calendar year in which the Option is outstanding at any time.

The purchase price for each share purchased will be 85% of the closing price of the Common Stock on (i) the first business day of such Plan Period or (ii) the Exercise Date, whichever closing price shall be less. Such closing price shall be (a) the closing price on any national securities exchange on which the Common Stock is listed, (b) the closing price of the Common Stock on the Nasdaq National Market or (c) the average of the closing bid and asked prices in the over-the-counter-market, whichever is applicable, as published in THE WALL STREET JOURNAL; PROVIDED, HOWEVER, that, with respect to the first Plan Period, the closing price on the Offering Commencement Date shall be the initial public offering price provided for in the underwriting agreement entered into by the Company in connection with the IPO. If no sales of Common Stock were made on such a day, the price of the Common Stock for purposes of clauses (a) and (b) above shall be the reported price for the next preceding day on which sales were

made.

Each employee who continues to be a participant in the Plan on the Exercise Date shall be deemed to have exercised his Option at the Option Price on such date and shall be deemed to have purchased from the Company the number of full shares of Common Stock reserved for the purpose of the Plan that his accumulated payroll deductions on such date will pay for, but not in excess of the maximum number determined in the manner set forth above.

Any balance remaining in an employee's payroll deduction account at the end of a Plan Period will be automatically refunded to the employee, except that any balance which is less than the purchase price of one share of Common Stock will be carried forward into the employee's payroll deduction account for the following Offering, unless the employee elects not to participate in the following Offering under the Plan, in which case the balance in the employee's account shall be refunded.

10. ISSUANCE OF CERTIFICATES. Certificates representing shares of Common Stock purchased under the Plan may be issued only in the name of the employee, in the name of the employee and another person of legal age as joint tenants with rights of survivorship, or (in the Company's sole discretion) in the name of a brokerage firm, bank or other nominee holder designated by the employee. The Company may, in its sole discretion and in compliance with

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applicable laws, authorize the use of book entry registration of shares in lieu of issuing stock certificates.

11. RIGHTS ON DEATH OR TERMINATION OF EMPLOYMENT. In the event of a participating employee's termination of employment prior to the last business day of a Plan Period, no payroll deduction shall be taken from any pay due and owing to an employee and the balance in the employee's account shall be paid to the employee or, in the event of the employee's death, (a) to a beneficiary previously designated in a revocable notice signed by the employee (with any spousal consent required under state law) or (b) in the absence of such a designated beneficiary, to the executor or administrator of the employee's estate or (c) if no such executor or administrator has been appointed to the knowledge of the Company, to such other person(s) as the Company may, in its discretion, designate. If, prior to the last business day of the Plan Period, the Designated Subsidiary by which an employee is employed shall cease to be a subsidiary of the Company, or if the employee is transferred to a subsidiary of the Company that is not a Designated Subsidiary, the employee shall be deemed to have terminated employment for the purposes of this Plan.

12. OPTIONEES NOT STOCKHOLDERS. Neither the granting of an Option to an employee nor the deductions from his pay shall constitute such employee a stockholder of the shares of Common Stock covered by an Option under this Plan until such shares have been purchased by and issued to him.

13. RIGHTS NOT TRANSFERABLE. Rights under this Plan are not transferable by a participating employee other than by will or the laws of descent and distribution, and are exercisable during the employee's lifetime only by the employee.

14. APPLICATION OF FUNDS. All funds received or held by the Company under this Plan may be combined with other corporate funds and may be used for any corporate purpose.

15. ADJUSTMENT IN CASE OF CHANGES AFFECTING COMMON STOCK. In the event of a subdivision of outstanding shares of Common Stock, or the payment of a dividend in Common Stock, the number of shares approved for this Plan, and the share limitation set forth in Section 9, shall be increased proportionately, and such other adjustment shall be made as may be deemed equitable by the Board or the Committee. In the event of any other change affecting the Common Stock, such adjustment shall be made as may be deemed equitable by the Board or the Committee to give proper effect to such event.

16. MERGER. If the Company shall at any time merge or consolidate with another corporation and the holders of the capital stock of the Company immediately prior to such merger or consolidation continue to hold at least 80% by voting power of the capital stock of the surviving corporation ("Continuity of Control"), the holder of each Option then outstanding will thereafter be entitled to receive at the next Exercise Date upon the exercise of such Option

for each share as to which such Option shall be exercised the securities or property which a holder of one share of the Common Stock was entitled to upon and at the time of such merger or consolidation, and the Board or the Committee shall take such steps in connection with such merger or consolidation as the Board or the Committee shall deem necessary to assure that the provisions of Section 15 shall thereafter be applicable, as nearly as reasonably may be, in

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relation to the said securities or property as to which such holder of such Option might thereafter be entitled to receive thereunder.

In the event of a merger or consolidation of the Company with or into another corporation which does not involve Continuity of Control, or of a sale of all or substantially all of the assets of the Company while unexercised Options remain outstanding under the Plan, (a) subject to the provisions of clauses (b) and (c), after the effective date of such transaction, each holder of an outstanding Option shall be entitled, upon exercise of such Option, to receive in lieu of shares of Common Stock, shares of such stock or other securities as the holders of shares of Common Stock received pursuant to the terms of such transaction; or (b) all outstanding Options may be cancelled by the Board or the Committee as of a date prior to the effective date of any such transaction and all payroll deductions shall be paid out to the participating employees; or (c) all outstanding Options may be cancelled by the Board or the Committee as of the effective date of any such transaction, provided that notice of such cancellation shall be given to each holder of an Option, and each holder of an Option shall have the right to exercise such Option in full based on payroll deductions then credited to his account as of a date determined by the Board or the Committee, which date shall not be less than ten (10) days preceding the effective date of such transaction.

17. AMENDMENT OF THE PLAN. The Board may at any time, and from time to time, amend this Plan in any respect, except that (a) if the approval of any such amendment by the stockholders of the Company is required by Section 423 of the Code, such amendment shall not be effected without such approval, and (b) in no event may any amendment be made which would cause the Plan to fail to comply with Section 423 of the Code.

18. INSUFFICIENT SHARES. In the event that the total number of shares of Common Stock specified in elections to be purchased under any Offering plus the number of shares purchased under previous Offerings under this Plan exceeds the maximum number of shares issuable under this Plan, the Board or the Committee will allot the shares then available on a pro rata basis.

19. TERMINATION OF THE PLAN. This Plan may be terminated at any time by the Board. Upon termination of this Plan all amounts in the accounts of participating employees shall be promptly refunded.

20. GOVERNMENTAL REGULATIONS. The Company's obligation to sell and deliver Common Stock under this Plan is subject to listing on a national stock exchange or quotation on the Nasdaq National Market (to the extent the Common Stock is then so listed or quoted) and the approval of all governmental authorities required in connection with the authorization, issuance or sale of such stock.

21. GOVERNING LAW. The Plan shall be governed by Delaware law except to the extent that such law is preempted by federal law.

22. ISSUANCE OF SHARES. Shares may be issued upon exercise of an Option from authorized but unissued Common Stock, from shares held in the treasury of the Company, or from any other proper source.

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23. NOTIFICATION UPON SALE OF SHARES. Each employee agrees, by entering the Plan, to promptly give the Company notice of any disposition of shares purchased under the Plan where such disposition occurs within two years after the date of grant of the Option pursuant to which such shares were purchased.

24. WITHHOLDING. Each employee shall, no later than the date of the event creating the tax liability, make provision satisfactory to the Board for payment of any taxes required by law to be withheld in connection with any

transaction related to Options granted to or shares acquired by such employee pursuant to the Plan. The Company may, to the extent permitted by law, deduct any such taxes from any payment of any kind otherwise due to an employee.

25. EFFECTIVE DATE AND APPROVAL OF STOCKHOLDERS. The Plan shall take effect on the Effective Date, subject to approval by the stockholders of the Company as required by Section 423 of the Code, which approval must occur within twelve months of the adoption of the Plan by the Board.

26. SPECIAL PROVISIONS FOR FIRST PLAN PERIOD. The following provisions of this Section 26 shall apply with respect to the first Plan Period notwithstanding any provision of the Plan to the contrary:

(a) Every eligible employee shall automatically become a participant in the Plan for the first Plan Period at the highest percentage of Compensation permitted under Section 5. No payroll deductions shall be required for the first Plan Period; HOWEVER, a participant may, at any time after the effectiveness of the Plan's Registration Statement on Form S-8, elect to have payroll deductions up to the aggregate amount which would have been credited to his or her account if a deduction of fifteen percent (15%) of the Compensation which he or she received on each pay day during the first Plan Period had been made (the "Maximum Amount") or decline to participate by filing an appropriate subscription agreement.

(b) Upon the automatic exercise of a participant's option on the Exercise Date for the First Plan Period, a participant shall be permitted to purchase shares with (i) the accumulated payroll deductions in his or her account, if any, (ii) a direct payment from the participant, or (iii) a combination thereof; PROVIDED, HOWEVER, that the total amount applied to the purchase may not exceed the Maximum Amount.

Adopted by the Board of Directors on March 8, 2004

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**Exhibit 23.1**

**CONSENT OF INDEPENDENT AUDITORS**

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated February 27, 2004 (except for Note 16, as to which the date is March 8, 2004), in Amendment No. 1 to the Registration Statement (Form S-1 No. 333-113522) and related Prospectus of Momenta Pharmaceuticals, Inc.

/s/ Ernst & Young LLP

Boston, Massachusetts  
April 15, 2004

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QuickLinks

[Exhibit 23.1](#)

[CONSENT OF INDEPENDENT AUDITORS](#)