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[TABLE OF CONTENTS](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2004

Commission File Number

0-50797

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

04-3561634

(I.R.S. Employer Identification No.)

43 Moulton Street, Cambridge, MA
(Address of Principal Executive Offices)

02138
(Zip Code)

(617) 491-9700

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

Indicate the number of shares outstanding of each of the Registrant's classes of Common Stock as of July 30, 2004:

Class	Number of Shares
Common Stock \$0.0001 par value	25,389,683



MOMENTA PHARMACEUTICALS, INC.
TABLE OF CONTENTS

	<u>Page</u>
<u>PART I. FINANCIAL INFORMATION</u>	1
<u>Unaudited Financial Statements</u>	1
Item 1.	1
<u>Balance Sheets as of June 30, 2004 and December 31, 2003 (unaudited)</u>	2
<u>Statements of Operations for the Three Months and Six Months Ended June 30, 2004 and 2003 (unaudited)</u>	3
<u>Statements of Cash Flows for the Six Months Ended June 30, 2004 and 2003 (unaudited)</u>	4
<u>Notes to Unaudited Financial Statements</u>	5
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	10
Item 2.	10
<u>Quantitative and Qualitative Disclosures About Market Risk</u>	37
Item 3.	37
<u>Controls and Procedures</u>	37
Item 4.	37
<u>PART II. OTHER INFORMATION</u>	38
<u>Legal Proceedings</u>	38
Item 1.	38
<u>Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities</u>	38
Item 2.	38
<u>Submission of Matters to a Vote of Security Holders</u>	39
Item 4.	39
<u>Exhibits and Reports on Form 8-K</u>	39
Item 6.	39
<u>SIGNATURES</u>	40

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Financial Statements.

MOMENTA PHARMACEUTICALS, INC.

BALANCE SHEETS

(in thousands, except share and per share amounts)

(unaudited)

Assets	June 30, 2004	December 31, 2003
Current assets:		
Cash and cash equivalents	\$ 41,046	\$ 4,613
Short-term investments	22,987	7,994
Unbilled collaboration revenue	2,104	2,018
Prepaid expenses and other current assets	980	262
	<hr/>	<hr/>
Total current assets	67,117	14,887
Property and equipment, net	1,341	1,117
Other assets	105	80
	<hr/>	<hr/>
Total assets	\$ 68,563	\$ 16,084
	<hr/>	<hr/>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 1,509	\$ 804
Accrued expenses	1,282	571
Deferred revenue	147	147
Line of credit obligation	329	321
	<hr/>	<hr/>
Total current liabilities	3,267	1,843
Deferred revenue-net of current portion	343	417
Line of credit obligation-net of current portion	205	372
Unvested restricted stock	4	6
	<hr/>	<hr/>
Total liabilities	3,819	2,638
Commitments and contingencies		
Redeemable convertible preferred stock, \$0.01 par value, issuable in series; 0 and 10,000,000 shares authorized at June 30, 2004 and December 31, 2003, respectively; 0 and 9,117,316 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	—	27,225
Stockholders' equity (deficit):		
Preferred stock, \$0.01 par value; 5,000,000 shares authorized and no shares issued and outstanding at June 30, 2004	—	—
Common stock, \$0.0001 par value; 100,000,000 and 20,000,000 shares authorized at June 30, 2004 and December 31, 2003, respectively; 25,389,683 and 4,162,805 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	3	—
Additional paid-in capital	112,080	4,960
Accumulated other comprehensive loss	(127)	(6)
Due from officer	(36)	(71)
Deferred compensation	(3,835)	(3,034)
Accumulated deficit	(43,341)	(15,628)
	<hr/>	<hr/>
Total stockholders' equity (deficit)	64,744	(13,779)
	<hr/>	<hr/>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 68,563	\$ 16,084
	<hr/>	<hr/>

See accompanying notes to unaudited financial statements.

MOMENTA PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Collaboration revenue	\$ 2,115	\$ —	\$ 3,151	\$ —
Operating expenses:				
Research and development*	3,508	938	5,748	1,728
General and administrative*	1,580	864	2,989	1,570
Total operating expenses	5,088	1,802	8,737	3,298
Loss from operations	(2,973)	(1,802)	(5,586)	(3,298)
Interest income	93	13	135	17
Interest expense	(10)	(12)	(21)	(18)
Net loss	(2,890)	(1,801)	(5,472)	(3,299)
Deemed dividend related to beneficial conversion feature of Series C redeemable convertible preferred stock	—	—	(20,389)	—
Dividends and accretion to redemption value of redeemable convertible preferred stock	(1,034)	(342)	(1,852)	(506)
Net loss attributable to common stockholders	\$ (3,924)	\$ (2,143)	\$ (27,713)	\$ (3,805)
Basic and diluted net loss attributable to common stockholders per common share	\$ (0.79)	\$ (1.14)	\$ (7.28)	\$ (2.27)
Shares used in computing basic and diluted net loss attributable to common stockholders per common share	4,985	1,881	3,808	1,679
*Includes stock-based compensation of the following:				
Research and development	\$ 108	\$ 26	\$ 199	\$ 48
General and administrative	635	124	953	242
Total stock-based compensation	\$ 743	\$ 150	\$ 1,152	\$ 290

See accompanying notes to unaudited financial statements.

MOMENTA PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

(in thousands)

(unaudited)

	Six Months Ended June 30,	
	2004	2003
Operating activities:		
Net loss	\$ (5,472)	\$ (3,299)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation	253	111
Stock compensation expense	1,152	292
Noncash interest expense	5	4
Amortization of premium on investments	350	—
Changes in operating assets and liabilities:		
Unbilled collaboration revenue	(86)	—
Prepaid expenses and other current assets	(718)	(74)
Other assets	(25)	46
Accounts payable	705	114
Accrued expenses	711	25
Deferred revenue	(74)	—
Net cash used in operating activities	(3,199)	(2,781)
Investing activities:		
Purchases of property and equipment	(477)	(205)
Purchases of marketable securities	(21,509)	—
Maturities of marketable securities	6,045	—
Net cash used in investing activities	(15,941)	(205)
Financing activities:		
Proceeds from initial public offering of common stock	35,297	—
Proceeds from issuance of redeemable convertible preferred stock, net of cash paid for issuance costs	20,390	18,900
Proceeds from line of credit	—	1,002
Payments on line of credit	(163)	(130)
Payment of officer obligation	35	36
Proceeds from exercise of stock options	14	1
Net cash provided by financing activities	55,573	19,809
Net increase in cash and cash equivalents	36,433	16,823
Cash and cash equivalents at beginning of period	4,613	1,471
Cash and cash equivalents at end of period	\$ 41,046	\$ 18,294

See accompanying notes to unaudited financial statements.

MOMENTA PHARMACEUTICALS, INC.

NOTES TO UNAUDITED FINANCIAL STATEMENTS

1. The Company

Business

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.

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting only of normal recurring accruals, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the three and six months ended June 30, 2004 are not necessarily indicative of the results that may be expected for the full year. These unaudited financial statements should be read in conjunction with the audited financial statements and related notes thereto included in the Company's Registration Statement on Form S-1, as amended, declared effective by the SEC on June 21, 2004.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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.

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

2. Summary of Significant Accounting Policies

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' equity (deficit). Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest earned on short-term investments is included in interest income.

Credit Risks and Concentrations

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

Revenue Recognition

Revenues resulting from the Company's collaboration agreement with the Sandoz N.V. and Sandoz Inc., each an affiliate of Novartis AG ("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 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.

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.

As set forth below, the pro forma disclosures of net loss allocable to common stockholders and loss per share allocable to common stockholders are as if the Company had adopted the fair value based method of accounting in accordance with SFAS No. 123, as amended by SFAS No. 148, which

assumes the fair value based method of accounting had been adopted (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss attributable to common stockholders as reported	\$ (3,924)	\$ (2,143)	\$ (27,713)	\$ (3,805)
Add: Stock-based employee compensation expenses included in net loss attributable to common stockholders	736	147	1,009	283
Deduct: Stock-based employee compensation determined under fair value based method	(682)	(53)	(852)	(94)
SFAS 123 Pro forma net loss	\$ (3,870)	\$ (2,049)	\$ (27,556)	\$ (3,616)
Basic and diluted net loss per share allocable to common stockholders:				
As reported	\$ (0.79)	\$ (1.14)	\$ (7.28)	\$ (2.27)
SFAS 123 Pro forma net loss	\$ (0.78)	\$ (1.09)	\$ (7.24)	\$ (2.15)

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. Components of comprehensive loss include net loss and unrealized losses on available-for-sale securities that have generally been reported in the statement of stockholders' equity. Comprehensive loss for the three months ended June 30, 2004 and 2003 was \$3.0 million and \$1.8 million, respectively. Comprehensive loss for the six months ended June 30, 2004 and 2003 was \$5.6 million and \$3.3 million, respectively.

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 available to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss available to common stockholders by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common stock equivalents consist of redeemable convertible preferred stock, stock options and warrants. Since the Company has a net loss for all periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share is the same.

The following table sets forth the computation of basic and diluted net loss per share for the respective periods (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net loss	\$ (2,890)	\$ (1,801)	\$ (5,472)	\$ (3,299)
Deemed dividend related to beneficial conversion feature of Series C redeemable convertible preferred stock	—	—	(20,389)	—
Dividends and accretion to redemption value of redeemable convertible preferred stock	(1,034)	(342)	(1,852)	(506)
Net loss attributable to common stockholders	\$ (3,924)	\$ (2,143)	\$ (27,713)	\$ (3,805)
Weighted average common shares used to compute basic and diluted net loss attributable to common stockholders per common share	4,985	1,881	3,808	1,679
Basic and diluted net loss attributable to common stockholders per common share	\$ (0.79)	\$ (1.14)	\$ (7.28)	\$ (2.27)

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 adoption of FIN 46 had no impact on its financial position or results of operations.

3. Stockholders' Equity and Redeemable Convertible Preferred Stock

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

On March 8, 2004, the Company's 2004 Stock Incentive Plan (the "Incentive Plan") was adopted by the Board of Directors and was approved by the Company's stockholders on June 10, 2004. Pursuant to the terms of the Incentive Plan, the Company is authorized to issue up to 3,948,785 shares of common stock with annual increases (to be added on the first day of the Company's fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013) of the lowest of (i) 1,974,393 shares, (ii) 5% of the then outstanding number of common shares or (iii) such other amount as the Board of Directors may authorize. On the same respective dates, the Company's Board of Directors and stockholders adopted and approved the Company's 2004 Employee Stock Purchase

Plan (the "Purchase Plan") pursuant to which the Company is authorized to issue up to 524,652 shares of common stock.

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read along with the unaudited financial statements and notes included in Item 1 of this Quarterly Report, as well as the audited financial statements and notes and Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal year ended December 31, 2003, included in our final prospectus dated June 21, 2004 for our initial public offering filed with the Securities and Exchange Commission. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding our results of operations, general and administrative expenses, research and development expenses, and the sufficiency of our cash for future operations. Words such as "we expect," "anticipate," "target," "project," "believe," "goals," "estimate," "potential," "predict," "may," "will," "expect," "might," "could," "intend," variations of these terms or the negative of those terms and similar expressions are intended to identify these forward-looking statements. Readers are cautioned that these forward-looking statements are predictions and are subject to risks, uncertainties, and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements.

Among the important factors that could cause actual results to differ materially from those indicated by our forward-looking statements are those discussed below under the subheading "Risk Factors That May Affect Results" and elsewhere in this report. We undertake no obligation to revise or update or revise publicly any forward-looking statement for any reason. Readers should carefully review the risk factors described in "Risk Factors That May Affect Results" below, as well as in the documents filed by us with the Securities and Exchange Commission, as they may be amended from time to time, including our final prospectus dated June 21, 2004.

Business 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. 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 most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox, the most widely prescribed low molecular weight heparin, or LMWH, in the world. 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 M-Enoxaparin.

Our revenues for the three and six months ended June 30, 2004 were \$2.1 million and \$3.2 million, respectively, consisting of amortization of the initial payment received under our collaboration agreement with Sandoz executed in November 2003 and amounts earned by us for reimbursement by Sandoz of research and development services and reimbursement of development costs for M-Enoxaparin.

Since our inception in May 2001 we have incurred annual net losses. As of June 30, 2004, we had an accumulated deficit of \$43.3 million. We recognized net losses of \$5.5 million for the first six months of 2004, \$7.9 million for the year ended December 31, 2003 and \$4.9 million for the year ended December 31, 2002. We expect to incur substantial and increasing losses for the next several years as

we develop our product candidates, expand our research and development activities and prepare for the commercial launch of our product candidates. 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 sale 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. On June 25, 2004, we completed an initial public offering of our common stock, the net proceeds of which were approximately \$35.3 million after deducting underwriters' discounts and expenses. We have devoted substantially all of our capital resources to the research and development of our product candidates.

Financial Operations Overview

Revenue

We have not yet generated any revenue from product sales and do not expect to generate any revenue from the sale of products over the next several years. We have recognized, in the aggregate, \$4.6 million of revenue from our inception through June 30, 2004. This revenue was derived entirely from our collaboration agreement with Sandoz executed in November 2003. 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 acute coronary syndromes, or 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 investigational new drug application, or IND, and begin Phase I clinical trials shortly thereafter. Because M118 is in preclinical development, we are not able to estimate the cost to complete the research and development phase nor are we able to estimate the timing of bringing M118 to market.

Other Development Opportunities. Other research programs include: applying a sugar-mediated technology to improve the non-invasive delivery of therapeutic proteins and applying capabilities which enable engineering of complex sugars on therapeutic proteins to improve the efficacy, reduce side effects and modify the dosage of protein drugs. In our drug discovery program, we are applying our understanding of sugar biology to develop sugar-based drugs and identify specific biological processes and pathways that can be targeted with small molecules and antibody drugs, focused initially on oncology.

General and Administrative

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

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.

Results of Operations

Three Months Ended June 30, 2004 and 2003

Revenue

Revenue for the three months ended June 30, 2004 was \$2.1 million, which was entirely attributable to our Sandoz collaboration. We had no revenues during the three months ended June 30, 2003.

Research and Development

The following table summarizes the primary components of our research and development expense for our principal research and development programs for the three months ended June 30, 2004 and 2003.

Research and Development Program	2004	2003
M-Enoxaparin	\$ 2,270	\$ 453
M118	642	20
Drug delivery	438	73
Other discovery and development programs	158	392
Total research and development expense	\$ 3,508	\$ 938

Research and development expense for the three months ended June 30, 2004 was \$3.5 million compared to \$0.9 million during the three months ended June 30, 2003. Our increase in research and development expenses principally resulted from increased manufacturing and personnel-related costs for the M-Enoxaparin program and the M118 development program. Manufacturing costs for M-Enoxaparin and M118 increased by \$1.2 million and \$0.4 million, respectively, and personnel and related costs due to increased headcount increased by \$0.5 million and \$0.1 million, respectively.

General and Administrative

General and administrative expense for the three months ended June 30, 2004 was \$1.6 million compared to \$0.9 million during the three months ended June 30, 2003. General and administrative expense increased due primarily to an increase in stock compensation expense of \$0.5 million.

Interest Income and Expense

Interest income increased to approximately \$93,000 for the three months ended June 30, 2004 from approximately \$13,000 for the three months ended June 30, 2003, primarily due to higher average investment balances in 2004 as a result of the proceeds from our issuance of Series B preferred stock in May 2003 and Series C preferred stock in February 2004. Interest expense decreased from approximately \$12,000 during the three months ended June 30, 2003 to approximately \$10,000 for the three months ended June 30, 2004 due to a lower average balance on our bank line of credit in the second quarter of 2004.

Six Months Ended June 30, 2004 and 2003

Revenue

Revenue for the six months ended June 30, 2004 was \$3.2 million, which was attributable to our collaboration agreement with Sandoz signed in November 2003. We had no revenues during the six months ended June 30, 2003.

Research and Development

The following table summarizes the primary components of our research and development expense for our principal research and development programs for the six months ended June 30, 2004 and 2003.

Research and Development Program	2004	2003
M-Enoxaparin	\$ 2,978	\$ 979
M118	1,429	65
Drug delivery	786	164
Other discovery and development programs	555	520
Total research and development expense	\$ 5,748	\$ 1,728

Research and development expense for the six months ended June 30, 2004 was \$5.7 million compared to \$1.7 million during the six months ended June 30, 2003. Our increase in research and development expenses principally resulted from increased manufacturing and personnel-related costs for the M-Enoxaparin program and the M118 development program. Manufacturing costs for M-Enoxaparin and M118 increased by \$1.4 million and \$0.9 million, respectively, and personnel and related costs due to increased headcount increased by \$0.5 million and \$0.3 million, respectively.

General and Administrative

General and administrative expense for the six months ended June 30, 2004 was \$3.0 million compared to \$1.6 million during the six months ended June 30, 2003. General and administrative expense increased due to an increase of \$0.7 million in stock compensation expense, an increase of \$0.4 million in personnel and related costs due to increased headcount, and an increase of \$0.2 million in professional fees due to an increase in consulting and legal fees.

Interest Income and Expense

Interest income increased to approximately \$135,000 for the six months ended June 30, 2004 from approximately \$17,000 during the six months ended June 30, 2003, primarily due to higher average investment balances in 2004 as a result of the proceeds from our issuance of Series B preferred stock in May 2003 and Series C preferred stock in February 2004. Interest expense increased from approximately \$18,000 during the six months ended June 30, 2003 to approximately \$21,000 during the six months ended June 30, 2004 due to a higher average balance on our bank line of credit in the 2004 period.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the private placements of equity securities and our initial public offering. From our inception through June 30, 2004, we have received net proceeds of \$45.4 million from the issuance of redeemable convertible preferred stock. In addition, on June 25, 2004, we completed our initial public offering and raised net proceeds of approximately \$35.3 million.

At June 30, 2004, we had \$64.0 million in cash, cash equivalents and short-term investments. Net cash used in operating activities was \$3.2 million and \$2.8 million for the six months ended June 30, 2004 and 2003, respectively. The use of cash in each period was primarily a result of net losses associated with our research and development activities and amounts incurred to develop our administrative infrastructure.

Net cash used in investing activities was \$15.9 million and \$0.2 million for the six months ended June 30, 2004 and 2003, respectively. In the first six months of 2004, we used \$21.5 million of cash to purchase short-term investments and had \$6.0 million in maturities of short-term investments. In the first six months of 2004 and 2003, we used \$0.5 million and \$0.2 million, respectively, to purchase equipment and leasehold improvements. We expect to use cash of approximately \$2.0 million for capital expenditures in 2004, principally related to the purchase of laboratory equipment and leasehold improvements.

In the first six months of 2004, our financing activities provided approximately \$55.6 million, reflecting the issuance of our Series C redeemable convertible preferred stock for net proceeds of \$20.4 million and our initial public offering for net proceeds of \$35.3 million. Net cash provided by financing activities was \$19.8 million for the six months ended June 30, 2003 primarily attributable to 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 repayments of \$0.1 million on the line of credit obligation.

We have signed a non-binding letter of intent with a third party to enter into a six 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: \$0.3 million; 2005 through 2006: \$3.5 million; 2007 through 2008: \$4.0 million; and after 2008: \$4.3 million.

We anticipate that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations through the first half of 2007. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially.

Funding Requirements

We have received \$3.0 million as of June 30, 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 our current cash, cash equivalents and short-term investments to continue the development of our product candidates, our discovery research programs and for other general corporate purposes, including:

- the approval and subsequent commercialization of near-term product candidates, including approximately \$8.0 million to \$10.0 million to develop M-Dalteparin through the filing of an ANDA;
- the development of improved product candidates, including using approximately \$12.0 million to \$15.0 million to develop M118 through Phase I and Phase IIa clinical trials and \$3.0 million to \$5.0 million for the initial development of pulmonary formulations of therapeutic proteins;
- the research and discovery of novel therapeutics and technologies; and
- working capital, capital expenditures and other general corporate purposes.

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

- the progress of development of M-Enoxaparin, M-Dalteparin and M118;
- the timing, receipt and amount of milestone and other payments, if any, from present and future collaborators;
- the time and costs involved in obtaining regulatory approvals;
- the continued progress in our research and development programs, including completion of our preclinical studies and clinical trials;
- the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;
- the potential acquisition and in-licensing of other technologies, products or assets;
- the timing, receipt and amount of sales and royalties, if any, from our product candidates;
- the cost of manufacturing, marketing and sales activities, if any; and
- the cost of litigation, including potential patent litigation.

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

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

If our existing resources are insufficient to satisfy our liquidity requirements or if we acquire or license additional technologies, products or assets that fit within our growth strategy, we may need to

raise additional external funds through the sale of equity or debt securities. The sale of equity securities may result in dilution to our stockholders. Additional financing may not be available in amounts or on terms acceptable to us or at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. 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 of equity instruments granted or sold by us. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

Revenue

We record revenue on an accrual basis as it is earned and when amounts are considered collectible. Revenues received in advance of performance obligations or in cases where we have a continuing obligation to perform services are deferred and recognized over the performance period. Revenues from milestone payments that represent the culmination of a separate earnings process are recorded when the milestone is achieved. Contract revenues are recorded as the services are performed. When we are required to defer revenue, the period over which such revenue should be recognized is subject to estimates by management and may change over the course of the collaborative agreement.

Accrued Expenses

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

Stock-Based Compensation

We have elected to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related interpretations, in accounting for our stock-based compensation plans, rather than the alternative fair value method provided for under Statement of Financial Accounting Standard No. 123, or SFAS 123, *Accounting for Stock-Based Compensation*. In 2003 and 2002, 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. For issuances prior to our initial public offering, which closed on June 25, 2004, market factors historically considered in valuing stock and stock option grants included comparative values of public companies discounted for the risk and limited liquidity provided for in the shares we 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.

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, the adoption of FIN 46 had no impact on our financial position or results of operations.

Risk Factors That May Affect Results

Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements contained or incorporated by reference in this Quarterly Report on Form 10-Q. Such factors that could cause or contribute to such differences include those factors discussed below. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. If any of the following risks actually occur, our business, prospects, financial condition and operating results would likely suffer, possibly materially.

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 June 30, 2004, our accumulated deficit was approximately \$43.3 million. We have not generated revenues from the sale of any products to date. We expect that our annual operating losses will increase over the next several years as we expand our drug commercialization, development and discovery efforts. To become profitable, we must successfully develop and obtain regulatory approval for our existing drug candidates, and effectively manufacture, market and sell any drug candidates we develop. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve profitability.

To become and remain profitable, we must succeed in developing and commercializing drugs with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages: developing drugs, obtaining regulatory approval for them, and manufacturing, marketing and selling them. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

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

We have invested a significant portion of our time, financial resources and collaboration efforts in the development of our most advanced candidate, M-Enoxaparin, a technology-enabled generic version of Lovenox. Our near-term ability to generate revenues and our future success, in part, depends on the development and commercialization of M-Enoxaparin.

We plan to prepare and submit an application to the FDA seeking to produce and market M-Enoxaparin in the United States. FDA approval of our application is required before marketing a generic equivalent of a drug previously approved under a new drug application, or NDA. If we are unable to obtain FDA approval for, and successfully commercialize M-Enoxaparin, we may never realize revenue from this product and we may have to curtail our other product development programs. As a result, our business would be materially harmed.

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

We will likely face costly and time consuming intellectual property litigation with Aventis, the innovator of Lovenox. Companies that produce branded pharmaceutical products for which there are unexpired patents listed in the FDA's Orange Book routinely bring patent infringement litigation against applicants seeking FDA approval to manufacture and market generic forms of their branded products. In August 2003, Aventis sued Amphastar Pharmaceuticals, Inc., or Amphastar, and Teva Pharmaceuticals USA, Inc., or Teva, alleging, among other things, that the generic versions of Lovenox intended to be marketed by those companies infringe Aventis' Patent No. 5,389,618, which is scheduled to expire on February 14, 2012. We expect to face patent litigation if and when we submit our regulatory application for a generic version of Lovenox to the FDA. Litigation often involves significant expense and could delay or prevent the introduction of a generic product. Under most circumstances, the decision as to when to begin marketing M-Enoxaparin will be determined jointly by us and Sandoz.

Sandoz, however, has sole discretion over the decision whether to market M-Enoxaparin under the following circumstance:

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

Should Sandoz elect to proceed in this manner, we could face substantial patent liability damages, including possible treble damages, if a final court decision is adverse to us. Sandoz has agreed to indemnify us for these liabilities, subject to Sandoz's ability to offset certain of these liabilities against the profit-sharing amounts, the royalties and the commercial milestone payments otherwise due to us from the marketing of M-Enoxaparin. Further, if we are unsuccessful in any litigation, the court could issue a permanent injunction preventing us from marketing M-Enoxaparin for the life of Aventis' patent. In addition, Aventis has significantly greater resources than we do, and litigation with Aventis could last a number of years, potentially delaying or prohibiting the commercialization of M-Enoxaparin. Intellectual property litigation involves many risks and uncertainties, and there is no assurance that we will prevail in any lawsuit brought by Aventis. If we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, we may have to curtail our product development programs and our business would be materially harmed.

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

Some of our products in current or future development may be based on new technologies that have not been formally reviewed or accepted by the FDA or other regulatory authorities. Given the complexity of our technology, we intend to work closely with the FDA and other regulatory authorities to perform the requisite scientific analysis and evaluation of our methods to obtain regulatory approval for our products. It is possible that the validation process may take time and resources, require independent third-party analysis or not be accepted by the FDA and other regulatory authorities. For some products, the regulatory approval path and requirements may not be clear, which could add significant delay and expense. Delays or failure to obtain regulatory approval of any of the products that we develop would adversely affect our business.

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

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

If we fail to meet manufacturing requirements for M-Enoxaparin, our development and commercialization efforts may be materially harmed.

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We have entered into an agreement with Siegfried (USA), Inc. and Siegfried Ltd., pursuant to which Siegfried is further developing our M-Enoxaparin laboratory-scale processes, manufacturing the drug substance for M-Enoxaparin and providing certain other development services relating to M-Enoxaparin. We expect to depend on additional third parties to manufacture the drug product and provide analytical services with respect to M-Enoxaparin. We have not yet completed the manufacturing of a sufficient number of registration lots of M-Enoxaparin necessary to file our regulatory submission and we may run into unforeseen difficulties that may cause a delay in the filing.

In addition, if the product is approved, in order to produce M-Enoxaparin in the quantities necessary to meet anticipated market demand, we and any contract manufacturer that we engage will need to increase manufacturing capacity. If we are unable to produce M-Enoxaparin in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, our revenues and gross margins could be adversely affected.

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

In addition to general competition in the pharmaceutical market, we expect that certain of our generic product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. Revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents for branded products and related exclusivity periods expire, manufacturers of generic products may receive regulatory approval for generic equivalents and may be able to achieve significant market penetration. As competing off-patent manufacturers receive regulatory approvals on similar products or as branded manufacturers launch generic versions of such products, market share, revenues and gross profit typically decline, in some cases, dramatically. If any of our generic product offerings, including M-Enoxaparin, enter markets with a number of competitors, we may not achieve significant market share, revenues or gross profit. In addition, as other generic products are introduced to the markets in which we participate, the market share, revenues and gross profit of our generic products could decline.

Competition in the biotechnology and pharmaceutical industries is intense, and if we are unable to compete effectively, our financial results will suffer.

The markets in which we intend to compete are undergoing, and are expected to continue to undergo, rapid and significant technological change. We expect competition to intensify as technological advances are made or new biotechnology products are introduced, such as alternatives to LMWHs or improved non-invasive delivery methods. New developments by competitors may render our current or future product candidates and/or technologies non-competitive, obsolete or not economical. Our competitors' products may be more efficacious or marketed and sold more effectively than any of our products.

The pharmaceutical market is highly competitive and rapidly changing. Many of our competitors have:

- significantly greater financial, technical and human resources than we have at every stage of the discovery, development, manufacturing and commercialization process;
- more extensive experience in commercializing generic drugs, preclinical testing, conducting clinical trials, obtaining regulatory approvals, challenging patents and in manufacturing and marketing pharmaceutical products;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

If we successfully develop and obtain approval for our drug candidates, we will face competition based on many different factors, including:

- the safety and effectiveness of our products;
- the timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the effectiveness of our marketing and sales capabilities;
- the price of our products;
- the availability and amount of third-party reimbursement; and
- the strength of our patent position.

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

If we are unable to establish and maintain our key customer arrangements, sales of our products and revenues would decline.

Most generic pharmaceutical products are sold to customers through arrangements with group purchasing organizations, or GPOs. Generic pharmaceuticals are also sold through arrangements with retail organizations, mail order channels and other distributors. Many of the hospitals which make up M-Enoxaparin's target market contract with the GPO of their choice for their purchasing needs. We expect to derive a large percentage of our future revenue for M-Enoxaparin from customers that have relationships with a small number of GPOs. Currently, a relatively small number of GPOs control a large majority of sales to hospital customers. In order to establish and maintain relationships with major GPOs, we believe we need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products. The GPOs with whom we hope to establish

relationships may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours. Typically, GPO agreements may be terminated on short notice. If we are unable to establish and maintain arrangements with major GPOs and customers, sales of our products, revenues and profits would decline.

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

Even if our drug candidates are successfully developed, our success and growth will also depend upon the acceptance of these drug candidates by physicians and third-party payors. Acceptance of our product development candidates will be a function of our products being clinically useful, being cost effective and demonstrating superior therapeutic effect with an acceptable side effect profile as compared to existing or future treatments. In addition, even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time.

Factors that we believe will materially affect market acceptance of our drug candidates under development include:

- the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration of our products;
- the competitive pricing of our products;
- the success of our physician education and marketing programs;
- the sales and marketing efforts of competitors; and
- the availability and amount of government and third-party payor reimbursement.

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

We will require substantial additional funds to execute our business plan and, if additional capital is not available, we may need to limit, scale back or cease our operations.

We will continue to require substantial funds to conduct research and development, preclinical testing and clinical trials of our development candidates, as well as funds necessary to manufacture and market any products that are approved for commercial sale. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Our future capital requirements may vary depending on the following:

- the progress of development of M-Enoxaparin, M-Dalteparin and M118;
- the cost of litigation, including potential patent litigation with Aventis relating to Lovenox, or with others, as well as any damages, including possibly treble damages, that may be owed to Aventis or others should we be unsuccessful in such litigation;
- the time and costs involved in obtaining regulatory approvals;
- the continued progress in our research and development programs, including completion of our preclinical studies and clinical trials;
- the potential acquisition and in-licensing of other technologies, products or assets; and
- the cost of manufacturing, marketing and sales activities, if any.

We anticipate that our current cash, cash equivalents and short-term investments, including \$20.4 million in net proceeds received in connection with the issuance of our Series C convertible preferred stock in February 2004, and the \$35.3 million in net proceeds from our initial public offering, will be sufficient to fund our operations through the first half of 2007. We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and debt financings. Additional funds may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

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

We are dependent on the members of our senior management team, in particular, Ganesh Venkataraman, our Founder and Vice President of Technology, for our business success. Our employment agreements with Dr. Venkataraman and our other executive officers are terminable on short notice or no notice. We do not carry life insurance on the lives of any of our personnel. The loss of any of our executive officers would result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and approval of our product candidates. In addition, our growth will require us to hire a significant number of qualified scientific, commercial and administrative personnel. There is intense competition from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions, for human resources, including management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful development and commercialization of our product candidates.

There is a substantial risk of product liability claims in our business. If we are unable to obtain sufficient insurance, a product liability claim against us could adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Product liability claims could delay or prevent completion of our development programs, clinical or otherwise. If we succeed in marketing products, such claims could result in a recall of our products or a change in the indications for which they may be used. We currently do not have any product liability insurance, but plan to obtain such insurance at appropriate levels prior to initiating studies in humans or clinical trials and at higher levels prior to marketing any of our drug candidates. Any insurance we obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts.

As we evolve from a company primarily involved in drug discovery and development into one that is also involved in the commercialization of drug products, we may have difficulty managing our growth and expanding our operations successfully.

As the development of our drug candidates advance, we will need to expand our development, regulatory, manufacturing, sales and marketing capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various collaborative partners, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. Such growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our

management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

Risks Relating to Development and Regulatory Approval

If we are not able to demonstrate therapeutic equivalence for our generic versions of complex drugs, including our M-Enoxaparin and our M-Dalteparin products to the satisfaction of the FDA, we will not obtain regulatory approval for commercial sale of our generic product candidates and our future results of operations would be adversely affected.

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and commercialize generic versions of complex drugs, including M-Enoxaparin and M-Dalteparin. To obtain regulatory approval for the commercial sale of our generic versions of complex drugs, including M-Enoxaparin and M-Dalteparin, we will be required to demonstrate to the satisfaction of the FDA, among other things, that our generic products contain the same active ingredients, are of the same dosage strength, form, and route of administration, and meet compendial or other applicable standards for strength, quality, purity and identity, including potency. Our generic versions of complex drugs, including M-Enoxaparin and M-Dalteparin, must also be bioequivalent, meaning generally that there are no significant differences in the rate and extent to which the active ingredients are absorbed and become available at the site of drug action. Under current regulations, for certain drug products where bioequivalence is self-evident such as injectable solutions which have been shown to contain the same active and inactive ingredients as the listed drug, the FDA may waive the requirement for in vivo bioequivalence data.

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

On February 19, 2003, a Citizen Petition was submitted to the FDA on behalf of Aventis requesting that the Commissioner of Food and Drugs withhold approval of any ANDA for a generic version of Lovenox until the conditions set forth in Aventis' petition are satisfied. In its petition, Aventis principally requested that, until enoxaparin has been fully characterized, the FDA refrain from approving any ANDA citing Lovenox as the reference listed drug, until the manufacturing process used to create the generic product is determined to be equivalent to Aventis' manufacturing process for Lovenox or the generic application is supported by proof of equivalent safety and effectiveness demonstrated through clinical trials. On February 12, 2004, Aventis submitted a supplement to its Citizen Petition, citing several new discoveries that supported its previous requests. To date, the FDA has not yet publicly responded to Aventis' requests nor has it issued any public interpretation of the guidelines for therapeutic equivalence as they may apply to LMWH products such as Lovenox or Fragmin. In the event that the FDA does not establish a standard for therapeutic equivalence with respect to generic versions of complex drugs, or requires us to conduct clinical trials or other lengthy processes, the commercialization of our technology-enabled generic product candidates could be delayed or prevented. Delays in any part of the process or our inability to obtain regulatory approval for our products could adversely affect our operating results by restricting or significantly delaying our introduction of new products.

If our preclinical studies and clinical trials for our development candidates are not successful, we will not be able to obtain regulatory approval for commercial sale of our novel or improved drug candidates.

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

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

We cannot predict whether any of our development candidates will encounter problems during clinical trials which will cause us or regulatory authorities to delay or suspend these trials, or which will delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate that is affected or the development of any of our other drug candidates.

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

Although we have not initiated any marketing efforts in foreign jurisdictions, we intend in the future to market our products outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approvals, our marketed drugs will be subject to ongoing regulatory review. If we fail to comply with continuing United States and foreign regulations, we could lose our approvals to market drugs and our business would be seriously harmed.

Even after approval, any drugs we develop will be subject to ongoing regulatory review, including the review of clinical results which are reported after our drug products are made commercially available. In addition, the manufacturer and manufacturing facilities we use to produce any of our drug candidates will be subject to periodic review and inspection by the FDA. We will be required to report any serious and unexpected adverse experiences and certain quality problems with our products and make other periodic reports to the FDA. The discovery of any previously unknown problems with the product, manufacturer or facility may result in restrictions on the drug or manufacturer or facility, including withdrawal of the drug from the market. Certain changes to an approved product, including in the way it is manufactured or promoted, often require prior FDA approval before the product as modified may be marketed. If we fail to comply with applicable continuing regulatory requirements, we may be subject to recalls, warning letters, civil penalties, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions and/or criminal prosecutions and penalties.

If third-party payors do not adequately reimburse customers for any of our product candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.

Our revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved product candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any drug product incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage does not imply that any product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our products.

The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for our products could have a material adverse effect on our operating results and our overall financial condition.

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

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changes the way Medicare will cover and reimburse for pharmaceutical products. The legislation expands Medicare coverage for drug purchases by the elderly and eventually will introduce a new reimbursement methodology based on average sales prices for drugs. In addition, the new legislation provides authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of the new legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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

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

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

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

If these efforts to delay or block competition are successful, we may be unable to sell our generic products, which could have a material adverse effect on our sales and profitability.

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

In some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development involves, and may in the future involve, the use of hazardous materials and chemicals, including sodium azide, cetylpyridinium chloride monohydrate, 4-chlorobenzyl chloride, sodium nitrite pyridine, sodium cyanoborohydride and barium acetate. For the six months

ended June 30, 2004 and for the fiscal years ended 2003, 2002 and 2001, we spent approximately \$6,000, \$17,500, \$10,000 and \$0, respectively, in order to comply with environmental and waste disposal regulations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the Commonwealth of Massachusetts to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. For claims not covered by workers' compensation insurance, we also maintain an employer's liability insurance policy in the amount of \$3.5 million per occurrence and in the aggregate. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Relating to Our Dependence on Third Parties

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

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

Sandoz may terminate our collaboration agreement for material uncured breaches or certain events of bankruptcy or insolvency by us. Sandoz may also terminate the collaboration agreement if the product or the market lacks commercial viability, if we fail to meet certain development milestones, if new laws or regulations are passed or court decisions rendered that substantially diminish our legal avenues for redress, or, in multiple cases, if certain costs exceed mutually agreed upon limits. If Sandoz terminates the agreement other than due to our uncured breach, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize injectable enoxaparin in the United States. In that event, we would need to expand our internal capabilities or enter into another collaboration. In such event, significant delays would be likely to occur and could prevent us from completing the development and commercialization of injectable enoxaparin.

If Sandoz terminates the agreement due to our uncured breach, Sandoz would retain the exclusive right to develop and commercialize injectable enoxaparin in the United States. In that event, although the profit sharing, royalty and milestone payment obligations of Sandoz would survive, we would no longer have any influence over the development or commercialization strategy. In addition, if Sandoz were to terminate the agreement due to our uncured breach, Sandoz would retain its rights of first negotiation with respect to certain of our other products in certain circumstances and its rights of first refusal outside of the United States. Accordingly, if Sandoz terminates the agreement, our introduction of M-Enoxaparin may be significantly delayed, we may decide to discontinue the M-Enoxaparin project, or our revenues may be reduced, any one of which could materially affect our business.

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

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. In addition, we do not have, and do not intend to develop, the ability to manufacture material for our clinical trials or at commercial scale. For our M-Enoxaparin program, we have entered into an agreement with Siegfried (USA), Inc. and Siegfried Ltd., pursuant to which, among other things, Siegfried will provide us with the M-Enoxaparin drug substance required for our ANDA filing. To develop our drug candidates, apply for regulatory approvals and commercialize any products, we or our partners need to contract for or otherwise arrange for the necessary manufacturing facilities and capabilities. As a result, we would generally rely on contract manufacturers for regulatory compliance and quality assurance for our products. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or drug candidates could be delayed, which could have an adverse effect 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, however, indemnify the parties for claims resulting from the negligence or willful misconduct of the indemnified party.

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

Risks Relating to Patents and Licenses

If we are not able to obtain and enforce patent protection for our discoveries, our ability to successfully commercialize our product candidates will be harmed and we may not be able to operate our business profitably.

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from using our inventions and proprietary information. However, we may not hold proprietary rights to some patents related to our current or future product candidates. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patent applications. As a result, we may be required to obtain licenses under third-party patents to market our proposed products. If licenses are not available to us on acceptable terms, or at all, we will not be able to market the affected products.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not guarantee that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not guarantee that we have the right to practice the patented invention. Third parties may have blocking patents that could be used to prevent us from marketing our own patented product and practicing our own patented technology.

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the United States Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims allowed in any patents issued to us or to others. The allowance of broader claims may increase the incidence and cost of patent interference proceedings and/or opposition proceedings, and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage. Moreover, once they have issued, our patents and any patent for which we have licensed or may license rights may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited, other companies will be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

Our competitors may allege that we are infringing their intellectual property, forcing us to expend substantial resources in resulting litigation, the outcome of which would be uncertain. Any unfavorable outcome of such litigation could have a material adverse effect on our business, financial position and results of operations.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to incur expenses to litigate the claims, pay damages, potentially including treble damages, if we are found to have willfully infringed such parties' patent rights. In addition, if we are unsuccessful in litigation, a court could issue a permanent injunction preventing us from marketing and selling the patented drug or other technology for the life of the patent that we have been deemed to have infringed. Litigation concerning patents, other forms of intellectual property and proprietary technologies is becoming more widespread and can be protracted and expensive, and can distract management and other key personnel from performing their duties for us.

Any legal action against us or our collaborators claiming damages and seeking to enjoin commercial activities relating to the affected products, and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain a license in order to continue to manufacture or market the affected products and processes. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, some licenses may be non-exclusive, and therefore, our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

If we become involved in patent litigation or other proceedings to enforce our patent rights, we could incur substantial costs, substantial liability for damages and be required to stop our product commercialization efforts.

We may need to resort to litigation to enforce a patent issued to us or to determine the scope and validity of third-party proprietary rights. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation could divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

We in-license a significant portion of our proprietary technologies and if we fail to comply with our obligations under any of the related agreements, we could lose license rights that are necessary to develop our product candidates.

We are a party to and rely on a number of in-license agreements with third parties, such as those with the Massachusetts Institute of Technology, that give us rights to intellectual property that is necessary for our business. In addition, we expect to enter into additional licenses in the future. Our current in-license arrangements impose various development, royalty and other obligations on us. If we breach these obligations, these exclusive licenses could be converted to non-exclusive licenses or the agreements could be terminated, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology.

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

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and

sponsored researchers, advisors and others. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

General Company Related Risks

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

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

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

If any of these factors causes an adverse effect on our business, results of operations or financial condition, the price of our common stock could fall and investors may not be able to sell their common stock at or above their respective purchase prices.

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

Our directors, executive officers and principal stockholders, together with their affiliates and related persons, beneficially owned, in the aggregate, approximately 68.7% of our outstanding common stock as of June 30, 2004. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company;

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

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

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

- a classified board of directors;
- a prohibition on actions by our stockholders by written consent;
- the ability of our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors and;
- limitations on the removal of directors.

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

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 sold in our initial public offering were 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. Substantially all of our remaining shares will be eligible for sale pursuant to Rule 144 upon the expiration of the 180-day lock-up agreements executed in connection with our initial public offering.

Holders of an aggregate of approximately 18,601,275 shares of common stock have rights with respect to the registration of their 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.

We have registered approximately 5,653,857 shares of common stock that are authorized for issuance under our stock plans, employee stock purchase plan and outstanding stock options. As of

June 30, 2004, 1,169,737 shares were subject to outstanding options. Because they are registered, the shares authorized for issuance under these plans 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of U.S. money market and high-grade corporate securities, directly or through managed funds, with maturities of twenty four months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. If market interest rates were to increase immediately and uniformly by 10% from levels at June 30, 2004, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. While our cash and investment balances have increased as a result of our initial public offering, we 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.

Item 4. Controls and Procedures.

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or Exchange Act) as of June 30, 2004. In designing and evaluating our disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our chief executive officer and chief financial officer concluded that, as of June 30, 2004, our disclosure controls and procedures were (1) designed to ensure that material information relating to us, including our consolidated subsidiaries, is made known to our chief executive officer and chief financial officer by others within those entities, particularly during the period in which this report was being prepared and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

(c) *Sales of Unregistered Securities*

During the three month period ended June 30, 2004, we issued and sold 29,438 shares of our common stock that were not registered under the Securities Act of 1933, as amended (the "Securities Act"), to our employees upon the exercise of options for cash consideration with an aggregate exercise price of \$6,758. During the same period, we granted options to purchase 133,480 shares of common stock at exercise prices ranging from \$0.98 per share to \$4.91 per share.

We did not employ an underwriter in connection with the issuance of the securities described above. We believe that the issuance of the foregoing securities was exempt from registration under either (i) Section 4(2) of the Securities Act as transactions not involving any public offering and such securities having been acquired for investment and not with a view to distribution, or (ii) Rule 701 under the Securities Act as transactions made pursuant to a written compensatory benefit plan or pursuant to a written contract relating to compensation. All recipients had adequate access to information about the Company. We registered the shares of common stock underlying the above-mentioned options on a Registration Statement on Form S-8 filed with the Securities and Exchange Commission on July 6, 2004.

(d) *Use of Proceeds from Registered Securities*

- (1) On June 25, 2004, we sold 5,350,000 shares, together with an additional 802,500 shares pursuant to the exercise by the underwriters of an over-allotment option, of our common stock in connection with the closing of our initial public offering (the "Offering"). The Registration Statement on Form S-1 (Reg. No. 333-113522) we filed to register our common stock in the Offering was declared effective by the Securities and Exchange Commission on June 21, 2004.
- (2) The Offering commenced as of June 21, 2004.
- (3) The Offering did not terminate before any securities were sold.
- (4)
 - (i) As of the date of the filing of this Quarterly Report, the Offering has terminated and all 6,152,500 shares of Common Stock registered were sold.
 - (ii) The managing underwriters in the Offering were SG Cowen & Co., LLC, Banc of America Securities LLC, CIBC World Markets Corp. and ThinkEquity Partners LLC.
 - (iii) We registered shares of our common stock in the Offering under the Securities Act of 1933, as amended.
 - (iv) All 6,152,500 shares of common stock (which includes 802,500 shares solely to cover over-allotments) registered in the Offering were sold at the full offering price per share of \$6.50. The aggregate purchase price of the Offering amount registered was \$39,991,250.

- (v) We incurred expenses in connection with the Offering of \$4.7 million, which consisted of direct payments of: (i) \$1.7 million in legal, accounting and printing fees; (ii) \$2.8 million in underwriters' discounts, fees and commissions; and (iii) \$0.2 million in miscellaneous expenses. No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.
- (vi) The net Offering proceeds to us after deducting total expenses were \$35.3 million.
- (vii) The net proceeds of the Offering have been invested into short-term investment-grade securities. None of the net proceeds were directly or indirectly paid to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.
- (viii) There has been no material change in the planned use of proceeds as described in our final prospectus.

Item 4. Submission of Matters to a Vote of Security Holders.

In June 2004, we sent a written consent to our stockholders requesting consent to the taking of the following actions in connection with the initial public offering of our common stock: (i) the approval of our Third Amended and Restated Certificate of Incorporation to be filed in connection with our initial public offering, (ii) the approval and adoption of our Second Amended and Restated Bylaws to become effective upon the closing of our initial public offering, (iii) the approval and adoption of our 2004 Stock Incentive Plan to become effective upon the closing of our initial public offering and reservation of 3,948,785 shares of common stock (post-split) initially available for issuance thereunder, and (iv) the approval and adoption of our 2004 Employee Stock Purchase Plan to become effective upon the closing of our initial public offering and reservation of 524,652 shares of common stock (post-split) available for issuance thereunder. All such actions were effected.

Item 6. Exhibits and Reports on Form 8-K.

(a) Exhibits

- 10.1 Form of Incentive Stock Option Agreement for 2004 Stock Incentive Plan.
- 10.2 Form of Nonstatutory Stock Option Agreement for 2004 Stock Incentive Plan.
- 10.3† Fourth Amendment to the Amended and Restated Exclusive Patent License Agreement, dated November 1, 2002, by and between the Massachusetts Institute of Technology and the Company.
- 10.4† Second Amendment to the Exclusive Patent License Agreement, dated October 31, 2002, by and between the Massachusetts Institute of Technology and the Company.
- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32 Certification Pursuant to 18 U.S.C. Section 1350.

(b) Reports on Form 8-K.

During the quarter ended June 30, 2004, the Company did not file any Current Reports on Form 8-K with the Securities and Exchange Commission.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Momenta Pharmaceuticals, Inc.

Date: August 16, 2004

By: /s/ Alan L. Crane

Alan L. Crane
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 16, 2004

By: /s/ Richard P. Shea

Richard P. Shea
Chief Financial Officer (Principal
Financial and Accounting Officer)

Momenta Pharmaceuticals, Inc.

**Incentive Stock Option Agreement
Granted Under 2004 Stock Incentive Plan**

1. Grant of Option.

This agreement evidences the grant by Momenta Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on [], 200[] (the "Grant Date") to [], an employee of the Company (the "Participant"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2004 Stock Incentive Plan (the "Plan"), a total of [] shares (the "Shares") of common stock, \$0.0001 par value per share, of the Company ("Common Stock") at \$[] per Share. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on [] (the "Final Exercise Date").

It is intended that the option evidenced by this agreement shall be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

This option will become exercisable ("vest") as to []% of the original number of Shares on the [] anniversary of the Grant Date and as to an additional []% of the original number of Shares at the end of each successive [] period following the first anniversary of the Grant Date until the [] anniversary of the Grant Date.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be by written notice in the form attached hereto as Exhibit A, in writing, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee or officer of, or consultant or advisor to, the Company or any parent or subsidiary of the Company as defined in Section 424(e) or (f) of the Code (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), *provided that* this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions

of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon written notice to the Participant from the Company describing such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), *provided that* this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Discharge for Cause. If the Participant, prior to the Final Exercise Date, is discharged by the Company for "cause" (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such discharge. "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been discharged for "Cause" if the Company determines, within 30 days after the Participant's resignation, that discharge for cause was warranted.

4. Tax Matters.

(a) Withholding. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

(b) Disqualifying Disposition. If the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

5. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this option.

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate seal by its duly authorized officer. This option shall take effect as a sealed instrument.

MOMENTA PHARMACEUTICALS, INC.

Dated: _____
By: _____
Name: _____
Title: _____

PARTICIPANT'S ACCEPTANCE

The undersigned hereby accepts the foregoing option and agrees to the terms and conditions thereof. The undersigned hereby acknowledges receipt of a copy of the Company's 2004 Stock Incentive Plan.

PARTICIPANT:

Address:

EXHIBIT A
NOTICE OF STOCK OPTION EXERCISE

Date: _____

Participant name and address:

Attention: Treasurer

Dear Sir or Madam:

I am the holder of an Incentive Stock Option granted to me under the Momenta Pharmaceuticals, Inc. (the "Company") 2004 Stock Incentive Plan on _____ for the purchase of _____ shares of Common Stock of the Company at a purchase price of \$_____ per share.

I hereby exercise my option to purchase _____ shares of Common Stock (the "Shares"), for which I have enclosed _____ in the amount of \$_____. Please register my stock certificate as follows:

(check applicable box)

Name(s):	_____	<input type="checkbox"/>	TEN COM
	_____	<input type="checkbox"/>	TEN ENT
Address:	_____	<input type="checkbox"/>	JT TEN
Tax I.D. #:	_____	<input type="checkbox"/>	UNIF GIFT MIN ACT

I represent, warrant and covenant as follows:

1. I am purchasing the Shares for my own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act of 1933 (the "Securities Act"), or any rule or regulation under the Securities Act.

2. I have had such opportunity as I have deemed adequate to obtain from representatives of the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company.
3. I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.
4. I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period.
5. I understand that (i) the Shares have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least one year and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

Very truly yours,

(Signature)

QuickLinks

[Exhibit 10.1](#)

[Momenta Pharmaceuticals, Inc. Incentive Stock Option Agreement Granted Under 2004 Stock Incentive Plan](#)

Momenta Pharmaceuticals, Inc.

**Nonstatutory Stock Option Agreement
Granted Under 2004 Stock Incentive Plan**

1. Grant of Option.

This agreement evidences the grant by Momenta Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on [], 200[] (the "Grant Date") to [], an **[employee]/[consultant] / [director]** of the Company (the "Participant"), of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2004 Stock Incentive Plan (the "Plan"), a total of [] shares (the "Shares") of common stock, \$0.0001 par value per share, of the Company ("Common Stock") at \$[] per Share. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on [] (the "Final Exercise Date").

It is intended that the option evidenced by this agreement shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

This option will become exercisable ("vest") as to []% of the original number of Shares on the [] anniversary of the Grant Date and as to an additional []% of the original number of Shares at the end of each successive [] period following the first anniversary of the Grant Date until the [] anniversary of the Grant Date.

The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be by written notice in the form attached hereto as Exhibit A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee, officer or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), *provided that* this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the

Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon written notice to the Participant from the Company describing such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee), *provided that* this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death or disability, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Discharge for Cause. If the Participant, prior to the Final Exercise Date, is discharged by the Company for "cause" (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such discharge. "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been discharged for "Cause" if the Company determines, within 30 days after the Participant's resignation, that discharge for cause was warranted.

4. Withholding.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

5. Nontransferability of Option.

This option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this option.

IN WITNESS WHEREOF, the Company has caused this option to be executed under its corporate seal by its duly authorized officer. This option shall take effect as a sealed instrument.

MOMENTA PHARMACEUTICALS, INC.

Dated:

By:

Name:

Title:

PARTICIPANT'S ACCEPTANCE

The undersigned hereby accepts the foregoing option and agrees to the terms and conditions thereof. The undersigned hereby acknowledges receipt of a copy of the Company's 2004 Stock Incentive Plan.

PARTICIPANT:

Address:

EXHIBIT A
NOTICE OF STOCK OPTION EXERCISE

Date: _____

Participant name and address:

Attention: Treasurer

Dear Sir or Madam:

I am the holder of an Nonstatutory Stock Option granted to me under the Momenta Pharmaceuticals, Inc. (the "Company") 2004 Stock Incentive Plan on _____ for the purchase of _____ shares of Common Stock of the Company at a purchase price of \$_____ per share.

I hereby exercise my option to purchase _____ shares of Common Stock (the "Shares"), for which I have enclosed _____ in the amount of \$_____. Please register my stock certificate as follows:

(check applicable box)

Name(s):	_____	<input type="checkbox"/>	TEN COM
	_____	<input type="checkbox"/>	TEN ENT
Address:	_____	<input type="checkbox"/>	JT TEN
Tax I.D. #:	_____	<input type="checkbox"/>	UNIF GIFT MIN ACT

I represent, warrant and covenant as follows:

1. I am purchasing the Shares for my own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act of 1933 (the "Securities Act"), or any rule or regulation under the Securities Act.

2. I have had such opportunity as I have deemed adequate to obtain from representatives of the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company.
3. I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.
4. I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period.
5. I understand that (i) the Shares have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least one year and even then will not be available unless a public market then exists for the Common Stock, adequate information concerning the Company is then available to the public, and other terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

Very truly yours,

(Signature)

QuickLinks

[Exhibit 10.2](#)

[Momenta Pharmaceuticals, Inc. Nonstatutory Stock Option Agreement Granted Under 2004 Stock Incentive Plan](#)

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

FOURTH AMENDMENT TO THE NOVEMBER 1, 2002 LICENSE

This Fourth Amendment, effective as of the date set forth above the signatures of the parties below, pertains to the Amended and Restated Exclusive Patent License Agreement, effective on November 1, 2002, as subsequently amended by a First Amendment on November 15, 2002, a Letter Agreement on September 12, 2003, a Letter Agreement on October 22, 2003, a Second Amendment on November 19, 2003 and a Third Amendment on April 2, 2004, by and between the Massachusetts Institute of Technology ("M.I.T.") and Momenta Pharmaceuticals, Inc. ("COMPANY").

WHEREAS, M.I.T. is the owner of certain new intellectual property closely related to the PATENT RIGHTS of the Amended and Restated Exclusive Patent License Agreement and desires to have this technology developed and commercialized to benefit the public; and

WHEREAS, COMPANY desires to add this new technology to the PATENT RIGHTS and M.I.T. is willing to grant a license thereunder.

NOW, THEREFORE, M.I.T. and COMPANY hereby agree to modify the Amended and Restated Exclusive Patent License Agreement as follows:

1. The patent rights of the following M.I.T. Case Nos. shall be added to the PATENT RIGHTS ENZYMES and the PATENT RIGHTS, as defined by their inclusion in the attached APPENDIX H:

*M.I.T. Case No. [**]
Entitled: [**]
By [**]*

*M.I.T. Case No. [**]
Entitled: [**]
By [**]*

*M.I.T. Case No. [**]
Entitled: [**]
By [**]*

2. In consideration of the addition of the patent rights of M.I.T. Case Nos. [**], and [**] to the PATENT RIGHTS ENZYMES and the license granted in the FIELD ENZYMES hereunder:

- a. COMPANY shall pay M.I.T. a Patent Addition Fee of [**] dollars (\$[**]) for each M.I.T. Case added for a total of [**] dollars (\$[**]), which shall be due within thirty (30) days of the Effective Date of this Fourth Amendment; and
- b. COMPANY shall be responsible for payment of all fees and costs relating to the filing, prosecution and maintenance of the patent rights of M.I.T. Case Nos. [**] and [**], whether such fees and costs were incurred [**] the Effective Date of this Fourth Amendment; provided, however, that should M.I.T. license the PATENT RIGHTS ENZYMES to one or more third parties, M.I.T. shall promptly notify COMPANY in writing and any fees and costs associated with PATENT RIGHTS ENZYMES shall be allocated in a fair and equitable manner between COMPANY and any subsequent licensees of the PATENT RIGHTS ENZYMES on a go-forward basis.

All other terms and conditions of the License Agreement shall remain unchanged.

The **EFFECTIVE DATE** of this Amendment is *July 17, 2004*.

Agreed to for:

MASSACHUSETTS INSTITUTE OF
TECHNOLOGY

By /s/ Lita L. Nelsen
Name Lita L. Nelsen
Title Technology Licensing Officer

Date July 26, 04

MOMENTA PHARMACEUTICALS, INC.

By /s/ Susan K. Whoriskey
Name Susan K. Whoriskey
Title Vice President, Licensing & Business
Development

Date July 28, 2004

APPENDIX H
PATENT RIGHTS ENZYMES

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

Patent Convention Treaty Serial No. [**]

United States of America Serial No. [**]

Entitled: [**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

Patent Convention Treaty Serial No. [**]

United States of America Serial No. [**]

Entitled: [**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

Japan Serial No. [**]

Patent Convention Treaty Serial No. [**]

United States of America Serial No. [**]

Entitled: [**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

[**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

United States of America Serial No. [**]

United States of America Serial No. [**]

Entitled: [**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

[**]

QuickLinks

[Exhibit 10.3](#)

[FOURTH AMENDMENT TO THE NOVEMBER 1, 2002 LICENSE
APPENDIX H PATENT RIGHTS ENZYMES](#)

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

SECOND AMENDMENT TO THE OCTOBER 31, 2002 LICENSE

This Second Amendment, effective as of the date set forth above the signatures of the parties below, pertains to the Exclusive Patent License Agreement, effective on October 31, 2002, and subsequently amended by a First Amendment dated November 15, 2002 by and between the Massachusetts Institute of Technology ("M.I.T.") and Momenta Pharmaceuticals, Inc. ("COMPANY").

WHEREAS, M.I.T. is the owner of certain new intellectual property closely related to the PATENT RIGHTS of the Exclusive Patent License Agreement and desires to have this technology developed and commercialized to benefit the public; and

WHEREAS, COMPANY desires to add this new technology to the PATENT RIGHTS and M.I.T. is willing to grant a license thereunder.

NOW, THEREFORE, M.I.T. and COMPANY hereby agree to modify the Exclusive Patent License Agreement as follows:

1. The patent rights of the following M.I.T. Case Nos. shall be added to the PATENT RIGHTS ENZYMES and the PATENT RIGHTS, as defined by their inclusion in the attached APPENDIX E:

*M.I.T. Case No. [**]
Entitled: [**]
By [**]*

*M.I.T. Case No. [**]
Entitled: [**]
By [**]*

*M.I.T. Case No. [**]
Entitled: "[**]"
By [**]*

2. In consideration of the addition of the patent rights of M.I.T. Case Nos. [**] and [**] to the PATENT RIGHTS ENZYMES and the license granted in the FIELD SEQUENCING MACHINES hereunder:

- a. COMPANY shall pay M.I.T. a Patent Addition Fee of [**] dollars (\$[**]) for each M.I.T. Case added for a total of [**] dollars (\$[**]), which shall be due within thirty (30) days of the Effective Date of this Second Amendment; and
- b. Should the First Agreement (as defined under Section 6.3) be terminated for any reason, COMPANY shall be responsible for payment of all fees and costs relating to the filing, prosecution and maintenance of patent rights of M.I.T. Case Nos. [**] and [**], whether such fees and costs were incurred [**] the Effective Date of this Second Amendment; provided, however, that should M.I.T. license the PATENT RIGHTS ENZYMES to one or more third parties in a field other than FIELD SEQUENCING MACHINES, M.I.T. shall promptly notify COMPANY in writing and any fees and costs associated with PATENT RIGHTS ENZYMES shall be allocated in a fair and equitable manner between COMPANY and any subsequent licensees of the PATENT RIGHTS ENZYMES on a go-forward basis.

All other terms and conditions of the License Agreement shall remain unchanged.

The **EFFECTIVE DATE** of this Amendment is *July 17, 2004*.

Agreed to for:

MASSACHUSETTS INSTITUTE OF
TECHNOLOGY

By /s/ Lita L. Nelsen
Name Lita L. Nelsen
Title Technology Licensing Officer

Date July 26, 04

MOMENTA PHARMACEUTICALS, INC.

By /s/ Susan K. Whoriskey
Name Susan K. Whoriskey
Title Vice President, Licensing & Business
Development

Date July 28, 2004

APPENDIX E
PATENT RIGHTS ENZYMES

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

Patent Convention Treaty Serial No. [**]

United States of America Serial No. [**]

Entitled: [**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

Patent Convention Treaty Serial No. [**]

United States of America Serial No. [**]

Entitled: [**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

Japan Serial No. [**]

Patent Convention Treaty Serial No. [**]

United States of America Serial No. [**]

Entitled: [**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

[**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

United States of America Serial No. [**]

United States of America Serial No. [**]

Entitled: [**]

*M.I.T. Case No. [**]*

Entitled: [**]

By [**]

[**]

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[Exhibit 10.4](#)

[APPENDIX E PATENT RIGHTS ENZYMES](#)

CERTIFICATION

I, Alan L. Crane, Chief Executive Officer of Momenta Pharmaceuticals, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34-47986];
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2004

By: /s/ Alan L. Crane

Chief Executive Officer

QuickLinks

[Exhibit 31.1](#)

[CERTIFICATION](#)

CERTIFICATION

I, Richard P. Shea, Chief Financial Officer of Momenta Pharmaceuticals, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) [Paragraph omitted in accordance with SEC transition instructions contained in SEC Release 34-47986];
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2004

By: /s/ Richard P. Shea

Richard P. Shea
Chief Financial Officer

QuickLinks

[Exhibit 31.2](#)

[CERTIFICATION](#)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Alan L. Crane, Chief Executive Officer of the Company, and Richard P. Shea, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to Momenta Pharmaceuticals, Inc. and will be retained by Momenta Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Date: August 16, 2004

By: /s/ Alan L. Crane

Alan L. Crane
Chief Executive Officer

Date: August 16, 2004

By: /s/ Richard P. Shea

Richard P. Shea
Chief Financial Officer

QuickLinks

[Exhibit 32](#)

[CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002](#)