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 September 30, 2005

Commission File Number 0-50797

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3561634**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
675 West Kendall Street, Cambridge, MA	**02142**
(Address of Principal Executive Offices)	(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 by check mark whether the registrant is a shell company (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 November 1, 2005.

Class	**Number of Shares**
Common Stock $0.0001 par value	30,462,710

MOMENTA PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited).

MOMENTA PHARMACEUTICALS, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2005	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 91,913	$ 11,678
Marketable securities	71,349	41,943
Accounts receivable	—	2,238
Unbilled collaboration revenue	2,920	2,801
Prepaid expenses and other current assets	1,969	1,456
Total current assets	168,151	60,116
Property and equipment, net of accumulated depreciation	4,977	2,723
Restricted cash	1,485	1,485
Other assets	5	6
Total assets	$ 174,618	$ 64,330
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,374	$ 3,489
Accrued expenses	2,374	1,611
Deferred revenue	147	147
Line of credit obligation	915	715
Lease liability	14	—
Total current liabilities	5,824	5,962
Deferred revenue-net of current portion	159	270
Line of credit obligation-net of current portion	1,831	1,105
Lease liability-net of current portion	24	—
Total liabilities	7,838	7,337
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value; 5,000,000 shares authorized and no shares issued and outstanding at September 30, 2005 and December 31, 2004	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at September 30, 2005 and December 31, 2004; 30,459,627 and 25,408,944 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	3	3
Additional paid-in capital	235,490	112,510
Deferred compensation	(2,301)	(3,381)
Due from officer	—	(36)
Accumulated other comprehensive loss	(117)	(159)
Accumulated deficit	(66,295)	(51,944)
Total stockholders' equity	166,780	56,993
Total liabilities and stockholders' equity	$ 174,618	$ 64,330

See accompanying notes to unaudited financial statements.

MOMENTA PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Collaboration revenue	$ 2,957	$ 1,843	$ 10,094	$ 4,994
Operating expenses:				
Research and development*	6,276	4,481	16,564	10,229
General and administrative*	3,728	1,852	9,499	4,841
Total operating expenses	10,004	6,333	26,063	15,070
Loss from operations	(7,047)	(4,490)	(15,969)	(10,076)
Interest income	1,097	230	1,730	365
Interest expense	(51)	(10)	(112)	(31)
Net loss	(6,001)	(4,270)	(14,351)	(9,742)
Deemed dividend related to beneficial conversion feature of Series C redeemable convertible preferred stock	—	—	—	(20,389)
Dividends and accretion to redemption value of redeemable convertible preferred stock	—	—	—	(1,852)
Net loss attributable to common stockholders	$ (6,001)	$ (4,270)	$ (14,351)	$ (31,983)
Basic and diluted net loss per share attributable to common stockholders	$ (0.21)	$ (0.18)	$ (0.55)	$ (2.99)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	28,736	24,309	26,253	10,691
*Includes stock-based compensation as follows:				
Research and development	$ 131	$ 120	$ 402	$ 319
General and administrative	376	247	1,107	1,200
Total stock-based compensation	$ 507	$ 367	$ 1,509	$ 1,519

See accompanying notes to unaudited financial statements.

MOMENTA PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (14,351)	$ (9,742)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	698	365
Stock compensation expense	1,509	1,519
Lease liability	39	—
Noncash interest expense	7	8
Amortization of premium on investments	872	656
Changes in operating assets and liabilities:		
Accounts receivable	2,238	—
Unbilled collaboration revenue	(119)	(220)
Prepaid expenses and other current assets	(513)	(1073)
Restricted Cash	—	(1,485)
Other assets	—	74
Accounts payable	(1,115)	1,444
Accrued expenses	763	482
Deferred revenue	(110)	(110)
Net cash used in operating activities	(10,082)	(8,082)
Cash flows from investing activities:		
Purchases of property and equipment	(2,952)	(1,342)
Purchases of marketable securities	(76,439)	(54,422)
Maturities of marketable securities	46,203	10,542
Net cash used in investing activities	(33,188)	(45,222)
Cash flows from financing activities:		
Proceeds from initial public offering of common stock, net of issuance costs	—	35,297
Proceeds from issuance of redeemable convertible preferred stock, net of cash paid for issuance costs	—	20,390
Proceeds from secondary public offering of common stock, net of issuance costs	122,327	—
Proceeds from line of credit	1,551	—
Principal payments on line of credit	(633)	(246)
Repayment of officer obligation	36	36
Proceeds from issuance of common stock	224	14
Net cash provided by financing activities	123,505	55,491
Net increase in cash and cash equivalents	80,235	2,187
Cash and cash equivalents at beginning of period	11,678	4,613
Cash and cash equivalents at end of period	$ 91,913	$ 6,800

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, or detailed structural analysis, and design of complex sugars for the development of generic and 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, as well as its ability to comply 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 nine months ended September 30, 2005 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2004, which was filed with the Securities and Exchange Commission ("SEC") on March 31, 2005.

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.

2. Summary of Significant Accounting Policies

Cash, Cash Equivalents, and Marketable Securities

The Company invests its excess cash in bank deposits, money market accounts, corporate debt securities and U.S. government obligations. The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents.

Cash equivalents are carried at fair value, which approximates cost, and primarily consist of money market funds maintained at major U.S. financial institutions.

All marketable securities, which primarily represent marketable debt securities, have been classified as "available-for-sale." Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive loss and reported as a separate component of stockholders' equity. 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 marketable securities is included in interest income.

Credit Risks and Concentrations

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

Revenue Recognition

The Company 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. Revenues associated with the Company's collaboration with Sandoz include an initial payment, reimbursement of development services and expenses, and potential future milestones, profit share, 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, profit share 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, *Accounting for Stock-Based Compensation—Transition and Disclosure—an amendment of FASB Statement No. 123*, which assumes the fair value based method of accounting had been adopted (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Net loss attributable to common stockholders as reported	$ (6,001)	$ (4,270)	$ (14,351)	$ (31,983)
Add: Stock-based employee compensation expenses included in net loss attributable to common stockholders	351	347	1,050	1,355
Deduct: Stock-based employee compensation determined under fair value based method	(750)	(291)	(1,634)	(1,144)
SFAS 123 Pro forma net loss	$ (6,400)	$ (4,214)	$ (14,935)	$ (31,772)
Basic and diluted net loss per share allocable to common stockholders:				
As reported	$ (0.21)	$ (0.18)	$ (0.55)	$ (2.99)
SFAS 123 Pro forma net loss	$ (0.22)	$ (0.17)	$ (0.57)	$ (2.97)

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 September 30, 2005 and 2004 was $6.0 million and $4.3 million, respectively. Comprehensive loss for the nine months ended September 30, 2005 and 2004 was $14.3 million and $9.8 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 equivalent shares 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.

Recently Issued Accounting Standards

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), Share-Based Payment, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be expensed based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123(R) must be adopted no later than the beginning of the first fiscal year beginning after June 15, 2005, irrespective of the entity's fiscal year. Early adoption will be permitted in periods in which financial statements have not yet been issued. The Company will adopt Statement 123(R) effective as of January 1, 2006.

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

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

3. Stock Offering

On July 21, 2005, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Morgan Stanley & Co. Incorporated, as representative of the several underwriters named in the Underwriting Agreement, relating to the sale and issuance of 4,827,300 shares of the Company's common stock. The Company granted to the underwriters an option to purchase up to an additional 724,095 shares of common stock within 30 days after the offering to cover over-allotments, which option was not exercised. The price to the public was $27.02 per share, and proceeds to the Company from the offering, net of expenses, were $122.3 million. The shares of common stock were issued pursuant to a Registration Statement on Form S-3 (File No. 333-126356) filed on July 1, 2005 with the Securities and Exchange Commission (the "Commission") and a Registration Statement on Form S-3 (File No. 333-126798) filed on July 21, 2005 with the Commission under Rule 462(b) of the Securities Act of 1933, as amended.

4. Line of Credit

In December 2004, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank (the "Bank"). Under the terms of the Loan Agreement, the Company could borrow up to an aggregate of $3.0 million through September 30, 2005 solely for reimbursement of purchases of Eligible Equipment, as defined under the Loan Agreement. In December 2004, the Company had approximately $1.5 million in borrowings outstanding under the Loan Agreement. In June 2005, the Company borrowed an additional $1.3 million under the Loan Agreement and in September 2005, the Company borrowed the remaining $0.2 million under the Loan Agreement.

5. Subsequent Event

Shareholders' Rights Agreement

Effective November 7, 2005, the Board of Directors of the Company declared a dividend of one right (collectively, the "Rights") to buy one one-thousandth of a share of newly designated Series A Junior Participating Preferred Stock ("Series A Junior Preferred Stock") for each outstanding share of the Company's common stock to stockholders of record at the close of business on November 18, 2005. Initially, the Rights are not exercisable and will be attached to all certificates representing outstanding shares of common stock, and no separate Rights Certificates will be distributed. The Rights will expire at the close of business on November 6, 2008 unless earlier redeemed or exchanged. Until a right is exercised, the holder thereof, as such, will have no rights as a stockholder of the Company, including the right to vote or to receive dividends. The rights are not immediately exercisable. Subject to the terms and conditions of the Rights Agreement entered into by the Company with American Stock Transfer & Trust Company, as Rights Agent (the "Rights Agreement"), the Rights will become exercisable upon the earlier of (1) 10 business days following the later of (a) the first date of a public announcement that a person or group (an "Acquiring Person") acquires, or obtained the right to acquire, beneficial ownership of 20 percent or more of the outstanding shares of common stock of the Company or (b) the first date on which an executive officer of the Company has actual knowledge that an Acquiring Person has become such or (2) 10 business days following the commencement of a tender offer or exchange offer that would result in a person or group beneficially owning more than 20 percent of the outstanding shares

of common stock of the Company. Each right entitles the holder to purchase one one-thousandth of a share of Series A Junior Preferred Stock at an initial purchase price of $125.00 in cash, subject to adjustment. In the event that any person or group becomes an Acquiring Person, unless the event causing the 20% threshold to be crossed is an offer permitted pursuant to the Rights Agreement, each Right not owned by the Acquiring Person will entitle its holder to receive, upon exercise, that number of shares of common stock of the Company (or in certain circumstances, cash, property or other securities of the Company) which equals the exercise price of the Right divided by 50% of the current market price (as defined in the Rights Agreement) per share of such common stock at the date of the occurrence of the event. In the event that, at any time after any person or group becomes an Acquiring Person, (i) the Company is consolidated with, or merged with and into, another entity and the Company is not the surviving entity of such consolidation or merger (other than a consolidation or merger which follows a Permitted Offer) or if the Company is the surviving entity, but shares of its outstanding Common Stock are changed or exchanged for stock or securities (of any other person) or cash or any other property, or (ii) more than 50% of the Company's assets or earning power is sold or transferred, each holder of a Right (except Rights which previously have been voided as set forth in the Rights Agreement) shall thereafter have the right to receive, upon exercise, that number of shares of common stock of the acquiring company which equals the exercise price of the Right divided by 50% of the current market price of such common stock at the date of the occurrence of the event.

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, 2004, included in the Company's Annual Report on Form 10-K 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, development and manufacturing efforts, regulatory filings and the sufficiency of our cash for future operations. Words such as "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.

Business Overview

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

candidates.

Our business strategy is to utilize revenue realized from applying our technology to near-term product opportunities, such as M-Enoxaparin and other complex mixtures, as a funding source for our development and discovery programs. Over the long term, we expect to generate value by leveraging our understanding of sugars to create novel therapeutics which address critical unmet medical needs in a wide range of disease areas, including oncology, cardiovascular disease, inflammation and immunology.

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox® (enoxaparin sodium injection), a widely prescribed low molecular weight heparin, or LMWH. We have formed a collaboration with Sandoz N.V. and Sandoz Inc., collectively Sandoz, affiliates of Novartis AG, to jointly develop, manufacture and commercialize M-Enoxaparin. In accordance with our collaboration with Sandoz, an Abbreviated New Drug Application, or ANDA, was submitted for M-Enoxaparin on August 29, 2005.

Our revenues for the three and nine months ended September 30, 2005 were $3.0 million and $10.1 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 September 30, 2005, we had an accumulated deficit of $66.3 million. 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 will 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. We have derived our revenues from our collaboration agreement with Sandoz. We have devoted substantially all of our capital resources to the research and development of our product candidates.

The biotechnology and pharmaceutical industries in which we compete are undergoing, and are expected to continue to undergo, rapid and significant technological change. We expect competition to intensify as technological advances are made or new biotechnology products are introduced. To become and remain profitable, we must succeed in developing and commercializing drugs with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages: developing drugs; obtaining regulatory approval for them; and manufacturing, marketing and selling them. We have invested a significant portion of our time, financial resources and collaboration efforts in the development of our most advanced product candidate, M-Enoxaparin. Our successful development and commercialization of M-Enoxaparin, in collaboration with Sandoz, depends on several factors, including: using our technology to demonstrate successfully to the FDA that M-Enoxaparin is therapeutically equivalent to Lovenox; meeting any other FDA requirements for approval for commercialization; successfully manufacturing M-Enoxaparin in a consistent and reproducible manner and at a commercial scale; manufacturing M-Enoxaparin cost-effectively; achieving a favorable outcome of potential litigation with Sanofi-Aventis relating to enoxaparin, if any; and achieving market acceptance of M-Enoxaparin in the medical community and with third-party payors.

Recent Developments

Financing

On July 21, 2005, we entered into an underwriting agreement, or the Underwriting Agreement, with Morgan Stanley & Co. Incorporated, as representative of the several underwriters named in the Underwriting Agreement, relating to the sale and issuance of 4,827,300 shares of our common stock. We granted to the underwriters an option to purchase up to an additional 724,095 shares of our common stock within 30 days after the offering to cover over-allotments, which option was not exercised. The price to the public was $27.02 per share, and proceeds to us from the offering, net of expenses, were approximately $122.3 million. The shares of common stock were issued pursuant to a Registration Statement on Form S-3 (File No. 333-126356) filed on July 1, 2005 with the Securities and Exchange Commission and a Registration Statement on Form S-3 (File No. 333-126798) filed on July 21, 2005 with the Securities and Exchange Commission under Rule 462(b) of the Securities Act of 1933, as amended.

Shareholders' Rights Agreement

Effective November 7, 2005, the Board of Directors of the Company declared a dividend of one right (collectively, the "Rights") to buy one one-thousandth of a share of newly designated Series A Junior Participating Preferred Stock ("Series A Junior Preferred Stock") for each outstanding share of the Company's common stock to stockholders of record at the close of business on November 18, 2005. Initially, the Rights are not exercisable and will be attached to all certificates representing outstanding shares of common stock, and no separate Rights Certificates will be distributed. The Rights will expire at the close of business on November 6, 2008 unless earlier redeemed or exchanged. Until a right is exercised, the holder thereof, as such, will have no rights as a stockholder of the Company,

including the right to vote or to receive dividends. The rights are not immediately exercisable. Subject to the terms and conditions of the Rights Agreement entered into by the Company with American Stock Transfer & Trust Company, as Rights Agent (the "Rights Agreement"), the Rights will become exercisable upon the earlier of (1) 10 business days following the later of (a) the first date of a public announcement that a person or group (an "Acquiring Person") acquires, or obtained the right to acquire, beneficial ownership of 20 percent or more of the outstanding shares of common stock of the Company or (b) the first date on which an executive officer of the Company has actual knowledge that an Acquiring Person has become such or (2) 10 business days following the commencement of a tender offer or exchange offer that would result in a person or group beneficially owning more than 20 percent of the outstanding shares of common stock of the Company. Each right entitles the holder to purchase one one-thousandth of a share of Series A Junior Preferred Stock at an initial purchase price of $125.00 in cash, subject to adjustment. In the event that any person or group becomes an Acquiring Person, unless the event causing the 20% threshold to be crossed is an offer permitted by the Rights Agreement, each Right not owned by the Acquiring Person will entitle its holder to receive, upon exercise, that number of shares of common stock of the Company (or in certain circumstances, cash, property or other securities of the Company) which equals the exercise price of the Right divided by 50% of the current market price (as defined in the Rights Agreement) per share of such common stock at the date of the occurrence of the event. In the event that, at any time after any person or group becomes an Acquiring Person, (i) the Company is consolidated with, or merged with and into, another entity and the Company is not the surviving entity of such consolidation or merger (other than a consolidation or merger which follows a Permitted Offer) or if the Company is the surviving entity, but shares of its outstanding Common Stock are changed or exchanged for stock or securities (of any other person) or cash or any other property, or (ii) more than 50% of the Company's assets or earning power is sold or transferred, each holder of a Right (except Rights which previously have been voided as set forth in the Rights Agreement) shall thereafter have the right to receive, upon exercise, that number of shares of common stock of the acquiring company which equals the exercise price of the Right divided by 50% of the current market price of such common stock at the date of the occurrence of the event.

Financial Operations Overview

Revenue

We have not yet generated any revenue from product sales and are uncertain whether or not we will generate any revenue from the sale of products over the next several years. We have recognized, in the aggregate, $19.4 million of revenue from our inception through September 30, 2005. This revenue was derived entirely from our collaboration agreement with Sandoz. We will seek to generate revenue from a combination of research and development payments, profit sharing payments, milestone payments and royalties in connection with our Sandoz collaboration and similar future collaborative or strategic relationships. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of research and development and other payments received under our collaborative or strategic relationships, and the amount and timing of payments we receive upon the sale of our products, to the extent any are successfully commercialized.

Research and Development

Research and development expenses consist of costs incurred in identifying, developing and testing product candidates. These expenses consist primarily of salaries and related expenses for personnel, license fees, consulting fees, contract research and manufacturing, and the costs of laboratory equipment and facilities. We expense research and development costs as incurred.

The following summarizes our primary research and development programs:

Development Programs:

M-Enoxaparin

Our most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox. Lovenox is a widely-prescribed LMWH used for the prevention and treatment of deep vein thrombosis, or DVT, and treatment of acute coronary syndromes, or ACS. 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. In accordance with our collaboration agreement with Sandoz, an ANDA was submitted to the FDA for M-Enoxaparin on August 29, 2005, seeking to market M-Enoxaparin in the United States.

Upon the receipt of an ANDA submission, the FDA commences its review of the ANDA. We anticipate that the FDA's review of the M-Enoxaparin ANDA will require, among other things, a review of our technology and characterization methodology as well as our manufacturing data. In parallel, Momenta in collaboration with Sandoz, is focused on activities related to supporting the ANDA submission and the FDA's review of the ANDA submission and preparing for the commercial launch of M-Enoxaparin, if and when approved, including addressing sales and marketing, manufacturing and supply chain objectives.

M118

M118 is a LMWH that we rationally designed to provide improved anti-clotting activity, an enhanced safety profile and more flexible administration to treat patients with ACS. In November 2004, we postponed preclinical testing of M118 in order to develop a more efficient and reproducible manufacturing process. Those efforts have resulted in a new process with improved yield and reproducibility and reduced cost, as compared to the prior manufacturing process. In September 2005, we initiated pre-investigational new drug, or IND, Good Laboratory Practices, toxicology studies for M118, and we expect that additional expenditures will be required to complete preclinical testing. If such preclinical testing is successful, we intend to file an IND in mid-2006 and begin Phase I clinical trials shortly thereafter, if the IND goes into effect. Because M118 is in preclinical development, we are not currently able to estimate the cost to complete the research and development phase nor are we able to estimate the timing of commercialization of M118.

Other Complex Mixtures

We are exploring the application of our technology to the analysis of other complex mixture drugs beyond heparins. Complex mixtures are composed of heterogeneous molecules that, due to their diversity, are difficult to fully characterize. For example, protein and antibody products containing sugars, or glycoproteins, contain heterogeneous branched sugars that vary from molecule to molecule. These sugars confer specific biological properties to the glycoprotein or antibody drug and can often comprise a significant portion of the mass of a molecule. We believe we can apply our technology to characterize the composition of these and other complex mixture drugs. We continue to advance our discussions related to a complex mixture agreement, however, we anticipate that the execution of a collaboration agreement will likely occur after the end of 2005.

M-Dalteparin

M-Dalteparin is targeted to be a technology-enabled generic version of Fragmin®, a LMWH product. Fragmin is indicated for the prevention of DVT and selected indications in ACS. Fragmin is marketed by Pfizer Inc. in Europe and by Kissei Pharmaceutical Co, Ltd. in Japan. In September 2005, Eisai Inc., a U.S. pharmaceutical subsidiary of Eisai Co. Ltd., announced that it had licensed the U.S. rights to Fragmin from Pfizer. We are currently reassessing the commercial opportunity for M-Dalteparin. We have reprioritized the program and have chosen not to actively pursue a commercial partnership in 2005 with respect to M-Dalteparin. We have reduced our internal resources for M-Dalteparin while we reassess our options to pursue commercialization of the product. Whether we submit an ANDA in 2006 for M-Dalteparin is subject to the outcome of our ongoing analysis. The total cost of development and commercialization and the timing of bringing M-Dalteparin to market are subject to uncertainties relating to the market growth for Fragmin, as well as the development, regulatory and legal approval processes.

Discovery Programs:

We are also applying our analytic capabilities for complex sugars to several discovery programs, including a drug delivery program and an oncology program. Through our drug delivery program, we have identified a mechanism by which sugars facilitate the transport of drugs across mucosal membranes, enabling the delivery of larger proteins and leading to higher levels of bioavailability, or levels of drug in the blood. We believe this sugar-mediated transport mechanism can be applied to a variety of marketed drugs and drug candidates. While our current focus is on the pulmonary delivery of therapeutic proteins where achieving adequate bioavailability has been a challenge, the technology has potentially broad application to the delivery of other drugs across other mucosal membranes.

A second discovery program is focused on the role that complex sugars play in biological systems, including regulating the development and progression of disease. Our initial focus is in cancer, which is a disease characterized by unregulated cell growth. Sugars play a part in the conversion of normal cells into cancerous cells, the regulation of tumor growth, and tumor invasion and metastasis. We believe that our technology can provide us with a better understanding of the role of sugars in disease, which we hope will enable us to discover novel sugar therapeutics, develop improved diagnostics for the detection of cancer, as well as to discover new disease mechanisms that can be targeted with small molecule or antibody drugs.

General and Administrative

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

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

Results of Operations

Three Months Ended September 30, 2005 and 2004

Revenue

Revenues for the three months ended September 30, 2005 and 2004, which were entirely attributable to our Sandoz collaboration, were $3.0 million and $1.8 million, respectively. These revenues consist of amounts earned by us for reimbursement by Sandoz of research and development services and reimbursement of development costs for M-Enoxaparin and amortization of the initial payment received under our collaboration agreement with Sandoz executed in November 2003.

Research and Development

The following table summarizes the primary components of our research and development expense for the three months ended September 30, 2005 and 2004:

Research and Development (in thousands)	2005	2004
Development programs	$ 4,263	3,616
Discovery programs	944	570
Other research	1,069	295
Total research and development expense	$ 6,276	$ 4,481

Research and development expense for the three months ended September 30, 2005 was $6.3 million compared to $4.5 million during the three months ended September 30, 2004. Research and development expenses have increased in all our programs. Development program expenses have increased by $0.6 million primarily due to increased personnel-related costs. Discovery program expenses have increased by $0.4 million primarily due to an increase in personnel related costs as well as an increase in facility related costs. Other research expense increased by $0.8 million, primarily due to an increase in consulting of $0.4 million, recruiting of $0.1 million, technology development of $0.1 million and other research costs of $0.2 million.

General and Administrative

General and administrative expense for the three months ended September 30, 2005 was $3.7 million compared to $1.9 million during the three months ended September 30, 2004. General and administrative expense increased primarily due to an increase in professional fees of $0.5 million, salaries and related costs of $0.7 million, consulting of $0.3 million, insurance coverage of $0.2 million and $0.1 million in patent and license fees.

Interest Income and Expense

Interest income increased to $1.1 million for the three months ended September 30, 2005 from $0.2 million for the three months ended September 30, 2004, due to higher average investment balances in 2005 primarily as a result of the proceeds from our secondary offering in July 2005. Interest expense increased from approximately $10,000 during the three months ended September 30, 2004 to approximately $51,000 for the three months ended September 30, 2005 due to the additional line of credit obligation in December 2004.

Nine Months Ended September 30, 2005 and 2004

Revenue

Revenues for the nine months ended September 30, 2005 and 2004, which were entirely attributable to our Sandoz collaboration, were $10.1 million and $5.0 million, respectively. These revenues consist of amounts earned by us for reimbursement by Sandoz of research and development services and reimbursement of development costs for M-Enoxaparin and amortization of the initial payment received under our collaboration agreement with Sandoz executed in November 2003.

Research and Development

The following table summarizes the primary components of our research and development expense for the nine months ended September 30, 2005 and 2004:

Research and Development (in thousands)	2005	2004
Development programs	$ 11,603	$ 8,043
Discovery programs	2,271	1,632
Other research	2,690	554
Total research and development expense	$ 16,564	$ 10,229

Research and development expense for the nine months ended September 30, 2005 was $16.6 million compared to $10.2 million during the nine months ended September 30, 2004. Research and development expenses have increased in all our programs. Development program expenses have increased by $3.6 million primarily due to an increase of $1.6 million in manufacturing costs and $1.7 million in personnel-related costs. Discovery program expenses have increased by $0.6 million primarily due to an increase in personnel related costs as well as an increase in facilities related costs. Other research expense increased by $2.1 million, primarily due to an increase in consulting of $1.0 million, recruiting of $0.4 million, lab supplies of $0.1 million and other research and development costs of $0.6 million.

General and Administrative

General and administrative expense for the nine months ended September 30, 2005 was $9.5 million compared to $4.8 million during the nine months ended September 30, 2004. General and administrative expense increased primarily due to an increase in professional fees of $2.6 million, salaries and related costs of $1.1 million and insurance coverage of $0.6 million.

Interest Income and Expense

Interest income increased to $1.7 million for the nine months ended September 30, 2005 from $0.4 million for the nine months ended September 30, 2004, due to higher average investment balances in 2005 primarily as a result of the proceeds from our secondary offering in July 2005. Interest expense increased from approximately $31,000 during the nine months ended September 30, 2004 to approximately $112,000 for the nine months ended September 30, 2005 due to the additional line of credit obligation in December 2004.

Liquidity and Capital Resources

In July 2005, we raised $122.3 million in a public offering, net of underwriters' fees, commissions and other offering costs from the sale of 4,827,300 shares of our common stock at a public offering price of $27.02 per share.

At September 30, 2005, we had $163.3 million in cash, cash equivalents and marketable securities. Net cash used in operating activities for the nine months ended September 30, 2005 and 2004 was $10.1 million and $8.1 million, respectively. The use of cash in each period was primarily a result of net losses associated with our research and development activities and administrative costs.

Net cash used in investing activities for the nine months ended September 30, 2005 and 2004 was $33.2 million and $45.2 million, respectively. In the first nine months of 2005, we used $76.4 million of cash to purchase marketable securities and had $46.2 million in maturities of marketable securities. In the first nine months of 2005 and 2004, we used $3.0 million and $1.3 million, respectively, to purchase equipment and leasehold improvements. At September 30, 2005, we have used all available funds under the $3.0 million equipment line of credit entered into in December 2004.

For the nine months ended September 30, 2005, our financing activities provided approximately $123.5 million, reflecting proceeds of $122.3 million from our secondary public offering of common stock in July 2005, $1.6 million from two drawdowns on our line of credit with a bank primarily to finance the purchase of equipment, $0.3 million from stock option exercises, purchases of common shares through our Employee Stock Purchase Plan and a repayment of an officer loan, offset by $0.6 million in principal payments on our line of credit obligation. For the nine months ended September 30, 2004, our financing activities provided $55.5 million, reflecting net proceeds of $35.3 million from our initial public offering in June, 2004, the issuance of our Series C redeemable convertible preferred stock for net proceeds of $20.4 million, $50,000 from stock option exercises and a repayment by an officer, offset by $0.2 million in principal payments on our line of credit obligation.

We anticipate that our current cash, cash equivalents and marketable securities, including the $122.3 million in net proceeds from our follow-on offering in July 2005, will be sufficient to fund our operations through at least the end of 2008. 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 $16.8 million as of September 30, 2005 from our collaboration with Sandoz. We did not receive payments from any collaborations prior to 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 if certain costs exceed mutually agreed upon limits.

We expect to use our current cash, cash equivalents and marketable securities to continue the development of our product candidates, our discovery research programs and for other general corporate purposes. We intend to use the majority of our cash to fund: our development programs, including M-Enoxaparin, the application of our technology to complex mixtures including glycoproteins, M118, and M-Dalteparin; our discovery programs, which are focused on identifying novel therapeutics and technologies; the potential acquisition of companies, products and technologies that complement our business; and working capital, capital expenditures and other general corporate purposes.

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

- the advancement of our generic product candidates and other development programs;
- 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 our development programs, including our generic product candidates and programs involving preclinical and clinical development;
- the receptivity of the capital markets to financings by biotechnology companies; and
- our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

If our existing resources and the proceeds of our initial public offering and July 2005 follow-on offering are insufficient to satisfy our liquidity requirements or if we acquire or license additional technologies, products or assets that fit within our growth strategy, we may need to raise additional external funds through the sale of equity or debt securities. The sale of equity securities may result in dilution to our stockholders. Additional financing may not be available in amounts or on terms acceptable to us or at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our financial condition and operating results.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent

assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an on-going basis, we evaluate our estimates and judgments, including those related to revenue, accrued expenses and certain equity instruments. Prior to our IPO, we also evaluated our estimates and judgments regarding the fair valuation assigned to our common stock. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue

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

Accrued Expenses

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

Stock-Based Compensation

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

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

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

Recently Issued Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board ("FASB") issued FASB Statement No. 123 (revised 2004), Share-Based Payment, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be expensed based on their fair values. Pro forma disclosure is no longer an alternative. Statement 123(R) must be adopted no later than the beginning of the first fiscal year beginning after June 15, 2005, irrespective of the entity's fiscal year. Early adoption will be permitted in periods in which financial statements have not yet been issued. We will adopt Statement 123(R) on January 1, 2006.

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

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

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 September 30, 2005, our accumulated deficit was approximately $66.3 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 drugs 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 cause the market price of our common stock to decrease and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

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

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

In accordance with our collaboration agreement with Sandoz, an ANDA was submitted to the FDA on August 29, 2005, seeking to market M-Enoxaparin in the United States. FDA approval of an ANDA is required before marketing of a generic equivalent of a drug previously

approved under a New Drug Application, or NDA. If we are unable to satisfactorily complete the necessary testing to demonstrate therapeutic equivalence, if the FDA disagrees with our characterization approach, does not agree that M-Enoxaparin is equivalent to Lovenox, or if we otherwise fail to meet FDA requirements for our ANDA, including but not limited to manufacturing and bioequivalence requirements, or 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 patent litigation with Sanofi-Aventis, the innovator of Lovenox.

In August 2003, Sanofi-Aventis sued Amphastar Pharmaceuticals, Inc., or Amphastar, and Teva Pharmaceuticals USA, Inc., or Teva, alleging, among other things, that their generic versions of Lovenox intended to be marketed by those companies infringe Sanofi-Aventis' Patent No. 5,389,618, which is scheduled to expire on February 14, 2012. These lawsuits had been consolidated and brought before the U.S. District Court for the Central District of California.

On June 14, 2005, Sanofi-Aventis received Reissue Patent No. RE38,743, which replaces U.S. Patent No. 5,389,618. Reissue Patent No. RE38,743 is scheduled to expire on February 14, 2012.

On June 15, 2005, the U.S. District Court for the Central District of California granted summary judgment to Amphastar finding that Sanofi-Aventis' U.S. Patent No. 5,389,618 is unenforceable due to Sanofi-Aventis' inequitable conduct before the United States Patent and Trademark Office.

Based on its June 15th decision, the U.S. District Court for the Central District of California entered final judgment on Amphastar's and Teva's claims that U.S. Patent No. 5,389,618 and Reissue Patent No. RE38,743 are unenforceable on the grounds of inequitable conduct. The District Court entered final judgment on July 26, 2005. In September 2005 Sanofi-Aventis filed an appeal of the District Court's decision and final judgment to the U.S. Court of Appeals for the Federal Circuit. Intellectual property litigation involves many uncertainties, and there is no assurance that the U.S. Court of Appeals for the Federal Circuit will affirm the District Court's decision that U.S. Patent No. 5,389,618 is unenforceable or rule that, by consequence, Reissue Patent No. RE38,743 is unenforceable.

Should the Court of Appeals reverse or remand the District Court's finding of inequitable conduct in connection with U.S. Patent No. 5,389,618 and if a paragraph IV certification has been or will be filed with our ANDA, we will likely face costly and time consuming patent litigation with Sanofi-Aventis, the holder of the NDA for Lovenox.

Companies that produce branded pharmaceutical products for which there are unexpired patents listed in the FDA's Orange Book most often bring patent infringement litigation against applicants seeking FDA approval to manufacture and market generic forms of their branded products before patent expiration. Under the circumstances described in the preceding paragraph, we will likely face patent litigation if a paragraph IV certification has been or will be filed with our ANDA to produce and market a generic version of Lovenox. 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 as to when to begin marketing M-Enoxaparin under certain circumstances.

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

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

Some of our products in current or future development including M-Enoxaparin may be based on new technologies that have not previously 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 facilitate the requisite scientific analysis and evaluation of our methods in order 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 of our products, the regulatory approval path and requirements may not be clear, which could add significant delay and expense. Delays or failure to obtain regulatory approval of any of the products that we develop would adversely affect our business.

If other generic versions of Lovenox are approved and successfully commercialized our business would suffer.

In mid-2003, Amphastar and Teva each filed ANDAs for generic versions of Lovenox with the FDA. Each ANDA included a paragraph IV certification. In addition, other third parties, including without limitation Sanofi-Aventis, may seek approval to market generic versions of Lovenox in the United States. If any of these parties obtains FDA approval for generic versions of Lovenox, we may not gain any competitive advantage and the price for the product may be lower. Also, we may never achieve significant market share for M-Enoxaparin if either Amphastar or Teva, or another third party, markets generic versions of Lovenox before us. Under the Hatch-Waxman Act, any developer of a generic drug that is considered first to have its ANDA accepted for review by the FDA, and whose filing includes a paragraph IV certification, may be eligible to receive a 180-day period of generic market exclusivity. In the event that any eligible 180-day exclusivity period has not begun and/or has not 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. Less favorable economic terms could be triggered under our collaboration with Sandoz if one or more third parties commercialize a generic version of Lovenox. Consequently, if other generic versions of Lovenox are approved and commercialized, our revenues would be reduced and, as a result, our business, including our future discovery and development programs, would suffer.

If we experience manufacturing difficulties or are unable to obtain sufficient quantities of raw materials or manufacture sufficient quantities of 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 depend upon third parties to provide for raw materials, to manufacture the drug substance, or active pharmaceutical ingredient, for M-Enoxaparin and to provide certain other services relating to M-Enoxaparin. We also depend on additional third parties to produce the final drug product and provide certain analytical services with respect to M-Enoxaparin. Manufacturing requirements, including but not limited to, reproducibility, validation and scale-up, must be addressed in order to satisfy FDA requirements necessary for approval and commercialization of M-Enoxaparin. 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 may need to increase manufacturing capacity. If we are unable to satisfy the FDA requirements for approval or 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.

We will need to develop or acquire additional technologies as part of our efforts to analyze the chemical composition of complex mixtures other than heparins.

To date, our analytical techniques and methods have been primarily focused on the characterization of complex mixtures comprised of linear sugars, such as those found in the heparin class of drugs. In order to adequately analyze other complex mixtures, such as glycoproteins, we will need to develop or acquire new technologies. Our inability to develop or acquire and apply these new technologies would limit our ability to work with biotechnology companies to help them better understand the chemical composition of their products, impair our ability to assist biotechnology companies in developing improved and next generation versions of existing products, and limit our ability to perform the analysis that we believe may be required to enable follow-on or equivalent versions of these biologics. Our inability to develop or acquire additional technology for the characterization of complex mixtures other than heparins could reduce the likelihood of our success developing other products.

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

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

Many of our competitors have:

- significantly greater financial, technical and human resources than we have at every stage of the discovery, development,

manufacturing and commercialization process;
- more extensive experience in commercializing generic drugs, 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 for our products; and
- the strength of our patent position.

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

If we are unable to establish and maintain 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, future sales of our products, revenues and profits would suffer.

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

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

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

- the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;
- the safety, efficacy and ease of administration of our products;
- the competitive pricing of our products;
- the success 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.

As of September 30, 2005, we had cash, cash equivalents and marketable securities totaling $163.3 million. For the nine months ended September 30, 2005, we had a net loss of $14.4 million and used cash in operating activities of $10.1 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, preclinical testing and clinical trials of our drug candidates, as well as funds necessary to manufacture and market any products that are approved for commercial sale. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Our future capital requirements may vary depending on the following:

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

We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and debt financings. Additional funds may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

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

We are dependent on the members of our senior management team, in particular, Ganesh Venkataraman, our Co-Founder and Senior Vice President, Research, and John Bishop, Vice President, Pharmaceutical Sciences and Manufacturing for our business success. Our employment arrangements with Dr. Venkataraman and Dr. Bishop and our other executive officers are terminable by either party on short notice or no notice. We do not carry life insurance on the lives of any of our personnel. The loss of any of our executive officers would result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and approval of our product candidates. In addition, 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 our existing product liability insurance is insufficient, a product liability claim against us that exceeds the amount of our insurance coverage could adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and marketing of human therapeutic products. Product liability claims could delay or prevent completion of our development programs, 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. While we currently maintain product liability insurance coverage that we believe is adequate for our current operations, we cannot be sure that such coverage will be adequate to cover any incident or all incidents. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. These liabilities could prevent or interfere with our product development and commercialization efforts.

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

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

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

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

- we may find that the acquired company or assets do not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;
- we may have difficulty integrating the operations and personnel of the acquired business, and may have difficulty retaining the key personnel of the acquired business;
- we may have difficulty incorporating the acquired technologies;
- we may encounter technical difficulties or failures with the performance of the acquired technologies or drug products;
- we may face product liability risks associated with the sale of the acquired company's products;
- our ongoing business and management's attention may be disrupted or diverted by transition or integration issues and the complexity of managing diverse locations;
- we may have difficulty maintaining uniform standards, internal controls, procedures and policies across locations;
- the acquisition may result in litigation from terminated employees or third-parties; and
- we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

These factors could have a material adverse effect on our business, results of operations and financial condition or cash flows, particularly in the case of a larger acquisition or multiple acquisitions in a short period of time. From time to time, we may enter into negotiations for acquisitions that are not ultimately consummated. Such negotiations could result in significant diversion of management time, as well as out-of-pocket costs.

The consideration paid in connection with an acquisition also affects our financial results. If we were to proceed with one or more significant acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash to consummate any acquisition. To the extent we issue shares of stock or other rights to purchase stock, including options or other rights, existing stockholders may be diluted and earnings per share may decrease. In addition, acquisitions may result in the incurrence of debt, large one-time write-offs (such as acquired in-process research and development costs) and restructuring charges. They may also result in goodwill and other intangible assets that are subject to impairment tests, which could result in future impairment charges.

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

We have a history of using broad-based employee stock option programs to hire, provide incentives for, and retain our workforce in a competitive marketplace. Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation," allows companies the choice of either using a fair value method of accounting for options that would result in expense recognition for all options granted, or using an intrinsic value method, as prescribed by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," or APB 25, with a pro forma disclosure of the impact on net income (loss) of using the fair value option expense recognition method. We have elected to apply APB 25, and, accordingly, we generally have not recognized any expense with respect to employee stock options as long as such options are granted at exercise prices equal to the fair value of our common stock on the date of grant.

In December 2004, the Financial Accounting Standards Board issued "Share-Based Payment," or Statement 123(R). Statement 123(R)

requires that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity instruments issued. In determining the fair value of options and other equity-based awards, companies may use different valuation models that may involve extensive and complex analysis. Statement 123(R) will be effective for us no later than January 1, 2006, which is the first day of our 2006 fiscal year. The Company will be adopting the "modified prospective method" when applying Statement 123(R). We currently expect that our adoption of Statement 123(R) will adversely affect our operating results to some extent in future periods.

Risks Relating to Development and Regulatory Approval

If we are not able to demonstrate therapeutic equivalence for our generic versions of complex drugs, including M-Enoxaparin, 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 will be adversely affected.

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and commercialize generic versions of complex drugs, including M-Enoxaparin. To obtain regulatory approval for the commercial sale of our generic versions of complex drugs, including M-Enoxaparin, 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 as the branded products upon which they are based, 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 (if we elect to pursue), must also be demonstrated through *in vivo* studies to be bioequivalent, meaning generally that there are no significant differences between the generic drug and its branded counterpart with respect to the rate and extent to which the active ingredients are absorbed and become available at the site of drug action.

Determination of the same active ingredients for our generic versions of complex drugs will be based on our demonstration of chemical equivalence to the respective reference listed drugs. The FDA may not agree that we have adequately characterized our products or that our products are equivalent to their respective branded drugs. The FDA may require confirmatory information including, for example, animal or human 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, time consuming 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 practices, or cGMP. We cannot predict whether any of our generic product candidates will meet FDA requirements for approval.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of Lovenox or other complex drug products, does not establish standards for therapeutic equivalence for generic versions of complex drug products, or requires us to conduct clinical trials or other lengthy processes, the commercialization of our technology-enabled generic product candidates could be delayed or prevented. Delays in any part of the process or our inability to obtain regulatory approval for our products could adversely affect our operating results by restricting or significantly delaying our introduction of new products.

If the FDA is not able to establish specific guidelines or arrive at a consensus regarding the scientific analyses required for characterizing complex protein drugs, and if the U.S. Congress does not take action to create an abbreviated regulatory pathway for follow-on protein products, then the uncertainty about the value of our glycoprotein program will be increased.

The regulatory climate for generic versions of protein products remains very uncertain. Currently, there is no established statutory or regulatory pathway which provides the FDA with the authority to approve generic versions of most protein drugs. Most therapeutic protein drugs were approved by the FDA under the Public Health Service Act through the use of Biologics License Applications, or BLAs. Unlike products approved through the use of NDAs, there is no provision in the Public Health Service Act for an abbreviated application that would permit approval of a follow-on protein product, and the FDA has stated it does not believe it has the authority to rely on prior BLA approvals or on their underlying data to approve a follow-on product. Moreover, even for proteins originally approved as NDAs, there is debate as to the data necessary to demonstrate the sameness required for ANDA approval. Judicial construction of the current law may impact the approval process for generic versions of proteins originally approved as NDAs. For example the FDA was recently sued in the United States District Court for the District of Columbia and the court was asked to enter a declaratory judgment that the section 505(b)(2) NDA pathway can be used for protein-based biologic drugs regulated under section 505 of the Federal Food, Drug, and Cosmetic Act. Although the FDA stated in February 2005, that it anticipated drafting several guidances and concept papers to address the scientific and regulatory issues related to approval of generic versions of therapeutic protein products that were approved under BLAs, the FDA indicated that the development of many of these documents would take several months or more. The FDA has since delayed providing guidance and has not specified a time frame in which it expects to do so, and to our knowledge, no drafts have yet been published for public comment. Moreover, we are hopeful that the U.S. Congress, based on guidance from the FDA, will establish a regulatory path sometime in the future for approval of generic versions of therapeutic protein products that were approved under BLAs. Failure of the FDA to establish standards or the U.S. Congress to enact legislation establishing a pathway for regulatory approval could reduce the value of our glycoprotein program.

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

To obtain regulatory approval for the commercial sale of our novel or improved drug candidates, we will be required to demonstrate through preclinical studies and clinical trials that our drug development candidates are safe and effective. Preclinical testing and clinical trials of new development candidates are lengthy and expensive and the historical failure rate for development candidates is high. The results from preclinical testing of a development candidate may not predict the results that will be obtained in human clinical trials. Clinical trials cannot commence until we submit an IND containing sufficient preclinical data and other information to support use in human subjects and the FDA allows the trials to go forward. Clinical trials must also be reviewed and approved by institutional review boards, or IRBs, for each clinical trial site before a development candidate may be used in a human trial at that site. We, the FDA or other applicable regulatory authorities or an IRB 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 warning letters, civil penalties, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions and/or criminal prosecutions and penalties.

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

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

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

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

There have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our products. The Centers for Medicare and Medicaid Services, or CMS, frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payors may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

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

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

The Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, changes the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for drugs that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expands Medicare coverage for drug purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered drugs, as well as provides authority for limiting the number of drugs that will be covered in any therapeutic class and for plan sponsors to negotiate prices with manufacturers and suppliers of covered drugs. As a result of the MMA and the expansion of federal coverage of drug products, we expect continuing pressure to contain and reduce costs of pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our products and could materially adversely affect our operating results and overall financial condition. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement policies, and any reduction in coverage or payment that results from the MMA may result in a similar reduction in coverage or payments from private payors.

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

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

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

- pursuing new patents for existing products which may be granted just before the expiration of one patent, which could extend patent protection for a number of years or otherwise delay the launch of generic drugs;

- submitting Citizen Petitions to request the Commissioner of Food and Drugs to take administrative action with respect to prospective and filed generic drug applications;

- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug standards;

- revising labels of existing products to reflect more specific descriptions of a drug; 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 and certain radioactive materials and related equipment. For the years ended December 31, 2004, 2003, and 2002, we spent approximately $25,000, $17,500, and $10,000, respectively, in order to comply with environmental and waste disposal regulations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the Commonwealth of Massachusetts to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. For claims not covered by workers' compensation insurance, we also maintain an employer's liability insurance policy in the amount of $3.5 million per occurrence and in the aggregate. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Relating to Our Dependence on Third Parties

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

In November 2003, we entered into a collaboration and license agreement with Sandoz to jointly develop and commercialize injectable enoxaparin and certain improved injectable forms of enoxaparin. Under the terms of the agreement, we and Sandoz agree to exclusively work with each other in the development and commercialization of injectable enoxaparin within the United States. We have also granted to Sandoz the right to negotiate additional rights for certain products under certain circumstances. 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. Recently, affiliates of Sandoz acquired Hexal AG and affiliates of Sandoz acquired Eon Labs, Inc. These acquisitions could negatively impact our collaboration with Sandoz.

Sandoz may terminate our collaboration agreement for material uncured breaches or certain events of bankruptcy or insolvency by us. Sandoz may also terminate the collaboration agreement if the product or the market lacks commercial viability, if new laws or regulations are passed or court decisions rendered that substantially diminish our legal avenues for redress, or, in multiple cases, if certain costs exceed mutually agreed upon limits. If Sandoz terminates the agreement other than due to our uncured breach, we will be granted an

exclusive license under certain intellectual property of Sandoz to develop and commercialize injectable enoxaparin in the United States. In that event, we would need to expand our internal capabilities or enter into another collaboration. In such event, significant delays would likely occur that 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 have a material adverse effect on our business.

We depend on third-parties for the manufacture of products. If in the future we encounter difficulties in our supply or manufacturing arrangements, our business may be materially adversely 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. 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 expect generally to rely on contract manufacturers for regulatory compliance. 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 a material 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 noncompliance may be compromised or delayed.

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

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

In addition to relying on a third party for its capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our drug candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop 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 are approved for marketing, than to products from their own development programs.

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

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate product revenues.

We do not have a sales organization and have no experience as a company in the sales, marketing and distribution of pharmaceutical products. There are risks involved with establishing our own sales and marketing capabilities, as well as entering into arrangements with third parties to perform these services. For example, developing a sales force is expensive and time consuming and could delay any product launch. In addition, to the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services, we will have less control over sales of our products, and our future revenues would depend heavily on the success of the efforts of these third parties.

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

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

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

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

We maintain insurance coverage which we believe may limit our obligations under these indemnification provisions. With respect to M-Enoxaparin, we are also protected under certain circumstances through the indemnification provided to us by Sandoz. However, should our obligation under an indemnification provision fall outside the scope of our insurance coverage, exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial position and results of operations could be materially 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 materially 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 party successfully asserts that our creation or use of proprietary technology infringes upon their intellectual property rights, we might be forced to incur expenses to litigate the claims and 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 the failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

General Company Related Risks

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 34% of our outstanding common stock as of September 30, 2005. 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;
- a "poison pill" in accordance with the Company's Shareholders Rights Plan 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.

Our stock price may be volatile, and purchasers of our common stock could incur substantial losses.

The stock market in general and the market prices for securities of biotechnology companies in particular have experienced extreme volatility that often have been unrelated or disproportionate to the operating performance of these companies. The trading price of our common stock has been, and is likely to continue to be, volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

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

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 September 30, 2005, 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 secondary public offering in July 2005, 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 of September 30, 2005. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e)

under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2005, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds

On June 25, 2004, we sold 5,350,000 shares, together with an additional 802,500 shares pursuant to the exercise by the underwriters of an over-allotment option, of our common stock in connection with the closing of our initial public offering (the "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.

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

Item 6. Exhibits.

10.1	Amendment, dated September 22, 2005, to Consulting Agreement dated October 4, 2004, between Bennett M. Shapiro and the Registrant.
10.2	Amendment, dated September 22, 2005, to Consulting Agreement dated September 18, 2002, as amended, between Peter Barton Hutt and the Registrant.
10.3	First Amendment, dated September 7, 2005, to Sublease Agreement dated September 14, 2004, by and between Vertex Pharmaceuticals Incorporated and the Registrant.
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.
32.1	Certification Pursuant to 18 U.S.C. Section 1350.

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: November 14, 2005

By: /s/ Alan L. Crane
Alan L. Crane, President and Chief Executive Officer (Principal Executive Officer)

Date: November 14, 2005

By: /s/ Richard P. Shea
Richard P. Shea, Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 10.1

[Momenta Pharmaceuticals, Inc. Letterhead]

September 7, 2005

Bennett M. Shapiro
532 LaGuardia Place
Suite 524
New York, NY 10012

Re: Consulting Agreement — Renewal

Dear Mr. Shapiro:

Reference is made to the Industry Consulting Agreement effective as of October 4, 2004 (the "Agreement") between Momenta Pharmaceuticals, Inc. ("Company") and you ("Consultant"). Capitalized terms used herein and not otherwise defined shall have the meanings given such terms in the Agreement. The parties hereby amend the Agreement as follows:

1. Company and Consultant hereby agree to extend the term of the Agreement, as listed in Paragraph 3 of Attachment A, for one additional year, commencing on October 4, 2005 and terminating on October 3, 2006 (the "1st Renewal Period"). The Agreement may be extended for additional periods by mutual written consent.

2. As full compensation for the consulting services rendered under the Agreement during the 1st Renewal Period, Company shall grant Consultant, under Company's 2004 Stock Incentive Plan and standard form of Non-Statutory Agreement, a non-statutory option to purchase, at fair market value on the date of grant, 4,000 shares of the common stock of Company, exercisable within three (3) years of the date of grant. Subject to any non-renewal or earlier termination of this Agreement, the 4,000 shares shall vest over a one-year period in 12 equal monthly installments, with the first installment vesting one month from the date of grant.

All other terms and conditions of the Agreement shall remain in full force and effect during the 1st Renewal Period.

If the foregoing is in conformity with your understanding, please sign both copies of this letter agreement and return to us for counter-signature, attention: Lisa Carron Shmerling, Deputy General Counsel. This letter agreement shall be deemed to be binding and effective, upon the terms specified herein, as of the date of the final signature below.

Very truly yours,

MOMENTA PHARMACEUTICALS, INC.

By: /s/ Susan K. Whoriskey
Susan K. Whoriskey
Vice President, Licensing and Business Development

Agreed and accepted:

By: /s/ Bennett M. Shapiro
Bennett M. Shapiro

Date: 9/20/05

Exhibit 10.2

[Momenta Pharmaceuticals, Inc. Letterhead]

September 7, 2005

Peter Barton Hutt, Esq.
c/o Covington & Burling
1201 Pennsylvania Avenue, NW
Washington, DC 20004

Re: Consulting Agreement – 3rd Renewal

Dear Mr. Hutt:

Reference is made to the Consulting Agreement effective dated September 18, 2002 between Momenta Pharmaceuticals, Inc. (formerly Mimeon, Inc.) ("Company") and you ("Consultant"), as exended and amended by the renewal agreements dated September 29, 2003 and October 4, 2004 (collectively, the "Agreement"). Capitalized terms used herein and not otherwise defined shall have the meanings given such terms in the Agreement. The parties hereby amend the Agreement as follows:

1. Pursuant to Section 4 of the Agreement, Company and Consultant hereby agree to extend the Term of the Agreement for one additional year, commencing on September 18, 2005 and terminating on September 17, 2006 (the "3rd Renewal Period"). Except as otherwise agreed to in this Letter Agreement, the same terms and conditions as are set forth in the Agreement shall apply to the rendering of Consulting Services during the 3rd Renewal Period.

2. As compensation for the Consulting Services during the 3rd Renewal Period, Consultant will be granted an additional non-statutory stock option to purchase 4,000 shares of the Common Stock of the Company, at an exercise price equal to the fair market value of a share of Common Stock on the date of grant by the Company, exercisable within three (3) years of the date of grant, with such option to vest in 12 equal monthly installments with the first installment vesting one month from the date of grant.

3. Paragraph 1 of Schedule A of the Agreement is hereby deleted in its entirety and hereby replaced with the following:

"1. Description of Consulting Services.

The Consultant shall provide such consulting services at the Company reasonably requests in connection with regulatory strategies for drug development and the operation of the Company's business."

4. All other terms and conditions of the Agreement shall remain in full force and effect during the 3rd Renewal Period.

If the foregoing is in conformity with your understanding, please sign both copies of this letter agreement and return to us for counter-signature, attention: Lisa Carron Shmerling, Deputy General Counsel. This letter agreement shall be deemed to be binding and effective, upon the terms specified herein, as of the date of the final signature below.

Very truly yours,

MOMENTA PHARMACEUTICALS, INC.

By: /s/ Richard P. Shea
Chief Financial Officer

Date: September 22, 2005

Agreed and accepted:

By: /s/ Peter Barton Hutt
Peter Barton Hutt, Esq.

Date: September 22, 2005

Exhibit 10.3

FIRST AMENDMENT TO SUBLEASE

THIS FIRST AMENDMENT TO SUBLEASE ("Amendment") is entered into as of this 7th day of September, 2005 by and between Vertex Pharmaceuticals Incorporated ("Sublandlord") and Momenta Pharmaceuticals, Inc. ("Subtenant").

R E C I T A L S

A. Sublandlord and Subtenant entered into a sublease, dated as of September 14, 2004 ("Sublease") in which Sublandlord subleased to Subtenant that certain real property on the fourth floor and the first floor ("Premises") of the building located at 675 West Kendall Street, Cambridge, Massachusetts ("Building"); and

B. The Sublease provided in Section 1(b) for the use of approximately 20,000 rentable square feet located on the third floor of the Building and defined in the Sublease as the "Temporary Premises" from the Commencement Date until three (3) business days after the delivery of the Sublease Premises to Subtenant with the Subtenant Improvements having been Substantially Completed at which time Subtenant was to vacate the Temporary Premises in accordance with the terms of the Sublease; and

C. Sublandlord has so delivered the Sublease Premises to Subtenant, but Subtenant desires to continue on a temporary basis to occupy the Temporary Premises as well as the Sublease Premises and Sublandlord has agreed to permit such occupancy by extending the period of such occupancy by Subtenant of the Temporary Premises on the terms and conditions set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Sublandlord and Subtenant, for themselves and their respective successors and assigns, covenant and agree as follows:

1. Extension of Temporary Premises Demise. The date on which Subtenant is obligated to vacate the Temporary Premises pursuant to Section 1(b) of the Sublease is changed from three (3) business days after delivery of the Sublease Premises to Subtenant to October 31, 2005 (the "Temporary Premises Expiration Date"). The first sentence of Section 1(c) is amended to add in the second line after the words "Sublease Premises" and before the word "only": "(and the Temporary Premises pursuant to Section 1(b) of this Sublease)".

2. Payment of Temporary Premises Fixed Rent. Subsection (i) of Schedule 1, "Rent," is amended to provide that Subtenant shall continue to pay Temporary Premises Fixed Rent through the Temporary Premises Expiration Date.

3. Subtenant's Share. The premises subleased to Subtenant, for the purpose of determining Subtenant's Share, as defined in the Defined Terms of the Sublease, shall include the Temporary Premises through the Temporary Premises Expiration Date, meaning that Subtenant's Share shall be determined during such time period by including the Rentable Square Footage of the Temporary Premises and the Rentable Square Footage of the Subtenant's Premises (subject to remeasurement pursuant to Section 1(l) of the Sublease) (Subtenant's Share

during such period (subject to remeasurement) therefore equaling Twenty Two and 36/100 percent (22.36%)).

4. Holding Over. In the event Subtenant remains in the Temporary Premises after the Temporary Premises Expiration Date, in addition to all rights and remedies available to Sublandlord at law and in equity, such continued occupancy shall constitute holding over of the Temporary Premises and shall be governed by Section 1(h) of the Sublease with respect to the Temporary Premises only (but not the Sublease Premises).

5. Definitions. Unless otherwise set forth in this Amendment, all capitalized terms shall have the same meaning as set forth in the Sublease.

6. Effective Date. This Amendment shall take effect as of the date on which Master Landlord consents in writing to this Amendment ("Effective Date").

7. Ratification. The Sublease, as amended hereby, is hereby ratified, confirmed and deemed in full force and effect in accordance with its terms. Each party represents to the other that such party (a) is currently unaware of any default by the other party under the Sublease; and (b) has full power and authority to execute and deliver this Amendment and this Amendment represents a valid and binding obligation of such party enforceable in accordance with its terms.

8. Multiple Counterparts. This Amendment may be executed in multiple counterparts, each of which when so executed and delivered shall be deemed to be originals and together shall constitute but one and the same instrument.

9. No Offer. Submission of this instrument for examination and signature by Subtenant does not constitute an offer to lease or a reservation of or option for lease, and this instrument is not effective as a sublease amendment or otherwise until executed and delivered by both Sublandlord and Subtenant and consented to by Master Landlord.

10. Commencement Date. Sublandlord and Subtenant agree that the Commencement Date of the Sublease was September 14, 2004 and that the Sublease Premises Rent Commencement Date has occurred.

11. Master Landlord Consent. BMR-675 West Kendall Street LLC, a Delaware limited liability company, as a successor to Kendall Square, LLC is the Master Landlord as defined in the Sublease under the Master Lease, also defined in the Sublease. Following the parties' execution of this Amendment, Sublandlord shall promptly submit this Amendment to the Master Landlord for its consent. The effectiveness of this Amendment is conditioned on the consent to this Amendment by Master Landlord as indicated by its execution of this Amendment in the space provided below (or the execution of another consent form reasonably satisfactory to Sublandlord and Subtenant). In the event Master Landlord affirmatively denies consent prior to October 31, 2005, Subtenant shall not be responsible for hold over rent with respect to the Temporary Premises for the time period from the Commencement Date through four (4) days following such denial, but continued occupancy thereafter shall constitute hold over with respect to the Temporary Premises only (but not the Sublease Premises).

IN WITNESS WHEREOF, the parties hereto have executed this instrument under seal as of the day and year first above written.

SUBLANDLORD:

VERTEX PHARMACEUTICALS
INCORPORATED

By: /s/ Kenneth S. Boger
Name: Kenneth S. Boger
Title: Senior VP & General Counsel

SUBTENANT:

MOMENTA PHARMACEUTICALS, INC.

By: /s/ Richard P. Shea
Name: Richard P. Shea
Title: Vice President, Treasurer & CFO

EXHIBIT A

MASTER LANDLORD CONSENT

The undersigned, BMR-675 West Kendall Street LLC, hereby consents to this First Amendment, subject to the terms and conditions of that certain Consent to Sublease dated as of September 14, 2004, by and between KS Parcel A, LLC (as predecessor-in-interest to Master Landlord), Sublandlord and Subtenant.

MASTER LANDLORD
BMR-675 WEST KENDALL STREET LLC

By: /s/ Gary A. Kreitzer
Name: Gary A. Kreitzer
Title: Executive Vice President

Exhibit 31.1

CERTIFICATIONS

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) [Not applicable];

(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 (the registrant's fourth fiscal quarter in the case of an annual report) 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: November 14, 2005

/s/ Alan L. Crane
Alan L. Crane
Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

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) [Not applicable];

(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 (the registrant's fourth fiscal quarter in the case of an annual report) 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: November 14, 2005

/s/ Richard P. Shea
Richard P. Shea
Chief Financial Officer

Exhibit 32.1

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 September 30, 2005 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.

/s/ Alan L. Crane
Alan L. Crane
Chief Executive Officer

Dated: November 14, 2005

/s/ Richard P. Shea
Richard P. Shea
Chief Financial Officer

Dated: November 14, 2005