MOMENTA PHARMACEUTICALS INC
Form 10-Q
November 08, 2007

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 20549**

# FORM 10-Q

**(MARK ONE)**

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

**For the quarterly period ended September 30, 2007**

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

**For the Transition Period from to**

**Commission File Number 000-50797**

# Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **04-3561634** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **675 West Kendall Street, Cambridge, 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 x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer x Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

Indicate the number of shares outstanding of each of the Registrant s classes of Common Stock as of November 5, 2007.

| **Class** | **Number of Shares** |
|---|---|
| Common Stock $0.0001 par value | 36,469,811 |

**MOMENTA PHARMACEUTICALS, INC.**

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**MOMENTA PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share amounts)

(unaudited)

| | September 30, 2007 | December 31, 2006 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 18,309 | $ 22,351 |
| Marketable securities | 123,003 | 168,914 |
| Accounts receivable | 1,486 | |
| Unbilled collaboration revenue | 4,521 | 4,727 |
| Prepaid expenses and other current assets | 2,550 | 2,069 |
| Total current assets | 149,869 | 198,061 |
| | | |
| Property and equipment, net of accumulated depreciation | 19,370 | 13,603 |
| Intangible assets, net | 3,591 | |
| Restricted cash | 4,685 | 4,685 |
| Other assets | 24 | 36 |
| Total assets | $ 177,539 | $ 216,385 |
| | | |
| **Liabilities and Stockholders Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 6,983 | $ 4,311 |
| Accrued expenses | 4,807 | 5,786 |
| Deferred revenue | 2,192 | 123 |
| Line of credit obligations | 823 | 883 |
| Capital lease obligations | 1,627 | 941 |
| Lease financing liability | 628 | 596 |
| Deferred rent | 174 | 122 |
| Other current liabilities | 2,000 | |
| Total current liabilities | 19,234 | 12,762 |
| | | |
| Deferred revenue, net of current portion | 10,754 | 13,552 |
| Line of credit obligations, net of current portion | 143 | 738 |
| Capital lease obligations, net of current portion | 6,515 | 3,998 |
| Lease financing liability, net of current portion | 1,845 | 2,321 |
| Deferred rent, net of current portion | 449 | 423 |
| Total liabilities | 38,940 | 33,794 |
| | | |
| Commitments and contingencies | | |
| | | |
| Stockholders equity: | | |

| | | | | |
|---|---|---|---|---|
| Preferred stock, $0.01 par value; 5,000 shares authorized at September 30, 2007 and December 31, 2006, 100 shares of Series A Junior Participating Preferred Stock, $0.01 par value designated and no shares issued and outstanding | | | | |
| Common stock, $0.0001 par value; 100,000 shares authorized, 36,453 and 36,098 shares issued and outstanding at September 30, 2007 and December 31, 2006, respectively | | 4 | | 4 |
| Additional paid-in capital | | 318,436 | | 308,061 |
| Accumulated other comprehensive income | | 269 | | 45 |
| Accumulated deficit | | (180,110) | | (125,519) |
| Total stockholders equity | | 138,599 | | 182,591 |
| Total liabilities and stockholders equity | $ | 177,539 | $ | 216,385 |

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

**MOMENTA PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share amounts)

(unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2007 | 2006 | 2007 | 2006 |
| Collaboration revenue | $ 5,145 | $ 4,058 | $ 11,563 | $ 11,962 |
| Operating expenses: | | | | |
| Research and development* | 19,547 | 10,684 | 50,307 | 33,600 |
| General and administrative* | 6,255 | 7,210 | 21,964 | 19,271 |
| Total operating expenses | 25,802 | 17,894 | 72,271 | 52,871 |
| Loss from operations | (20,657) | (13,836) | (60,708) | (40,909) |
| Other income (expense): | | | | |
| Interest income | 2,003 | 1,981 | 6,688 | 5,318 |
| Interest expense | (214) | (160) | (571) | (339) |
| Net loss | $ (18,868) | $ (12,015) | $ (54,591) | $ (35,930) |
| Basic and diluted net loss per share | $ (0.53) | $ (0.37) | $ (1.53) | $ (1.15) |
| Shares used in computing basic and diluted net loss per share | 35,664 | 32,334 | 35,621 | 31,292 |

| | | | | |
|---|---|---|---|---|
| *Includes the following stock-based compensation expense: | | | | |
| Research and development | $ 1,041 | $ 934 | $ 3,558 | $ 3,078 |
| General and administrative | $ 1,644 | $ 1,105 | $ 6,080 | $ 4,361 |

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

**MOMENTA PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

(unaudited)

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2007** | **2006** |
| **Operating activities:** | | |
| Net loss | $ (54,591) | $ (35,930) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 2,395 | 1,264 |
| Stock-based compensation expense | 9,638 | 7,439 |
| (Accretion of discount) amortization of premium on investments | (4,936) | 42 |
| Purchase of in-process research and development | 737 | |
| Amortization of intangible assets | 172 | |
| Loss (gain) on disposal of assets | 43 | (4) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,486) | |
| Unbilled collaboration revenue | 206 | (748) |
| Prepaid expenses and other current assets | (481) | 732 |
| Restricted cash | | (2,907) |
| Other assets | 12 | 6 |
| Accounts payable | 2,672 | 92 |
| Accrued expenses | (979) | 2,468 |
| Deferred rent | 78 | 204 |
| Deferred revenue | (729) | 13,441 |
| Net cash used in operating activities | (47,249) | (13,901) |
| | | |
| **Investing activities:** | | |
| Purchase of intangible assets | (2,500) | |
| Purchases of property and equipment | (8,205) | (6,835) |
| Purchases of marketable securities | (195,229) | (141,133) |
| Maturities of marketable securities | 246,300 | 141,927 |
| Net cash provided by (used in) investing activities | 40,366 | (6,041) |
| | | |
| **Financing activities:** | | |
| Proceeds from issuance of common stock to Sandoz, net of issuance costs | | 61,384 |
| Proceeds from issuance of common stock under stock plans | 737 | 1,155 |
| Proceeds from financing of leasehold improvements | | 3,199 |
| Payments on financed leasehold improvements | (444) | (140) |
| Proceeds from capital lease obligations | 3,978 | 1,495 |
| Principal payments on capital lease obligations | (775) | (306) |
| Principal payments on line of credit | (655) | (635) |
| Net cash provided by financing activities | 2,841 | 66,152 |
| Net (decrease) increase in cash and cash equivalents | (4,042) | 46,210 |
| Cash and cash equivalents, beginning of period | 22,351 | 25,890 |
| Cash and cash equivalents, end of period | $ 18,309 | $ 72,100 |
| | | |
| **Supplemental disclosure of noncash investing activities:** | | |
| Accrued milestone payments to Parivid | $ 2,000 | $ |

The accompanying notes are an integral part of these unaudited, condensed consolidated financial statements.

**MOMENTA PHARMACEUTICALS, INC.**

**NOTES TO UNAUDITED, CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

## 1. The Company

***Business***

Momenta Pharmaceuticals, Inc. (the Company or Momenta ) was incorporated in the state of Delaware on May 17, 2001 and began operations in early 2002. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the detailed structural analysis of complex mixture drugs, applying its technology to the development of generic or follow-on versions of complex drug products as well as to the discovery and development of novel drugs.

***Basis of Presentation***

The accompanying unaudited, condensed consolidated 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 nine months ended September 30, 2007 are not necessarily indicative of the results that may be expected for the full year. These unaudited, condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2006, which was filed with the Securities and Exchange Commission ( SEC ) on March 15, 2007.

## 2. Summary of Significant Accounting Policies

***Use of Estimates***

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

***Cash, Cash Equivalents, and Marketable Securities***

The Company invests its excess cash in bank deposits, money market accounts, corporate debt securities and U.S. government obligations. The Company considers all highly liquid investments purchased with maturities of three months or less from the date of purchase to be cash equivalents. Cash equivalents are carried at fair value, which approximates cost, and primarily consist of money market funds maintained at major U.S. financial institutions. All marketable securities, which primarily represent marketable debt securities, have been classified as available-for-sale. Purchased premiums or discounts on debt securities are amortized to interest income through the stated maturities of the debt securities. Management determines the appropriate classification of its investments in marketable 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 income (loss), which is 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.

***Long-Lived Assets***

The Company evaluates the recoverability of its property, equipment and intangible assets when circumstances indicate that an event of impairment may have occurred in accordance with the provisions of Statement of Financial Accounting Standards ( SFAS ) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, or SFAS 144, which provides that companies (1) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (2) measure an impairment loss as the difference between the carrying amount and fair value of the asset. Impairment is measured based on the difference between the carrying value of the related assets or businesses and the undiscounted future cash flows of such assets or businesses. In addition, SFAS 144 provides guidance on accounting and disclosure issues surrounding long-lived assets to be disposed of by sale. No impairment charges have been required to be recognized through September 30, 2007.

***Revenue Recognition***

The Company recognizes revenue from research and development collaboration agreements in accordance with the SEC s Staff

Accounting Bulletin ( SAB ) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force ( EITF ) No. 00-21, *Revenue Arrangements With Multiple Deliverables*, or EITF 00-21.

Under the terms of collaboration agreements entered into by the Company, the Company may receive non-refundable, up-front license fees, funding or reimbursement of research and development efforts, milestone payments if specified objectives are achieved and/or profit-sharing or royalties on product sales. Agreements containing multiple elements are divided into separate units of accounting if certain criteria are met, including whether the delivered element has stand-alone value to the collaborative partner and whether there is objective and reliable evidence of fair value of the undelivered obligation(s). The consideration received is then allocated among the separate units based on either their respective fair values or the residual method, and the applicable revenue recognition criteria are applied to each of the separate units.

Revenues from non-refundable, up-front license fees are recognized on a straight-line basis over the contracted or estimated period of performance, which is typically the development term. Research and development funding is recognized as earned over the period of effort.

Any milestone payments are recognized as revenue upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone and (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone. If any of these conditions are not met, the milestone payment is deferred and recognized as revenue over the estimated remaining period of performance under the contract as the Company completes its performance obligations. Royalty and/or profit-share revenue, if any, is recognized based upon actual and estimated net sales of licensed products in licensed territories as provided by the licensee and in the period the sales occur. The Company has not recognized any milestone, royalty or profit-share revenue to date.

***Research and Development***

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

***Stock-Based Compensation***

Pursuant to the terms of the Company s 2004 Stock Incentive Plan, as amended (the Incentive Plan ), at December 31, 2006 the Company was authorized to issue up to 3,948,785 shares of common stock with annual increases (to be added on the first day of the Company s fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013) equal to the lowest of (i) 1,974,393 shares, (ii) 5% of the then outstanding number of common shares or (iii) such other amount as the Board of Directors may authorize. Effective January 1, 2007, the Company s Board of Directors increased the number of authorized shares by 1,802,053.

On January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share Based Payment*, or SFAS 123R, using the modified prospective method. Under that method, compensation cost recognized in the nine months ended September 30, 2007 includes (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in

accordance with the provisions of SFAS 123R. In accordance with SFAS 123R, the estimated grant date fair value of each stock-based award is recognized as expense on a ratable basis over the requisite service period (generally the vesting period).

In accordance with SFAS 123R, the fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton option-pricing model. Because of the Company s limited history as a publicly-traded company, to estimate expected volatility the Company used a blend of its own historic and implied volatility (75%) and an average of historic and implied volatilities of similar entities (25%). For purposes of identifying similar entities, the Company considered characteristics such as industry, stage of life cycle and financial leverage. As the Company continues to accumulate more of its own volatility data, the Company has increased its percentage weight of volatility relative to its identified peer company data. The expected term of option awards granted is derived from the average of the vesting and the contractual terms, as described in the SAB No. 107, *Share-Based Payment*. In the future, as information regarding post-vesting termination becomes more accessible, the Company will change its method of deriving the expected term. This change could impact the Company s fair value of option awards granted in the future. The Company expects to refine its method of deriving expected term no later than January 1, 2008. The risk-free interest rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

In addition, the Company applies an expected forfeiture rate when amortizing stock-based compensation expense. The Company s estimate of the forfeiture rate is based primarily upon annualized pre-vest termination rates. Pre-vest termination rates are calculated monthly by dividing the total number of options that were both unvested at the beginning of the month and that were cancelled by the total number of options that were unvested at the beginning of the month. These monthly rates are averaged and then annualized.

The unvested shares held by consultants have been and will be revalued using the Company s estimate of fair value at each balance sheet date pursuant to EITF Issue No. 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. The charge to operations is recorded in accordance with Financial Accounting Standards Board ( FASB ) Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*.

Restricted stock awards are measured on the date of grant based on the market value of the Company s common stock at that date and recognized as compensation expense over the explicit or implicit service periods.

***Income Taxes***

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

The Company adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109*, or FIN 48, effective January 1, 2007. The Company did not recognize any liability for unrecognized tax benefits as a result of adopting FIN 48. The Company recognizes both accrued interest and penalties related to unrecognized tax benefits in income tax expense. The Company did not recognize any interest and penalties in the three- or nine month periods ended September 30, 2007 and 2006, or since inception.

The Company files income tax returns in the United States federal jurisdiction and in the Commonwealth of Massachusetts. The Company is no longer subject to any tax assessment from an income tax examination for years before 2003, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2003. The Company currently is not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

***Comprehensive Loss***

The Company reports comprehensive loss in accordance with SFAS No. 130, *Reporting Comprehensive Income*, or SFAS 130. SFAS 130 establishes rules for the reporting and display of comprehensive income (loss) and its components. Accumulated other comprehensive income as of September 30, 2007 and 2006 consists entirely of unrealized gains and losses on available-for-sale securities. Comprehensive loss for the three months ended September 30, 2007 and 2006 was $18.7 million and $11.8 million, respectively. Comprehensive loss for the nine months ended September 30, 2007 and 2006 was $54.4 million and $35.6 million, respectively.

***Net Loss Per Share***

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings per Share,* or SFAS 128. Under the provisions of SFAS 128, basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the reporting period. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common stock equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock and shares issuable upon the exercise of stock options and stock 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 common share is the same.

***Segment Reporting***

SFAS No. 131, *Disclosure About Segments of an Enterprise and Related Information*, requires companies to report selected information about operating segments, as well as enterprise-wide disclosures about products, services, geographical areas, and major customers. Operating segments are determined based on the way management organizes its business for making operating decisions and assessing performance. The Company has only one operating segment, the discovery, development and commercialization of drug products. All of the Company s revenues through September 30, 2007 have come from one collaborative partner.

## 3. Asset Purchase

On April 20, 2007, the Company entered into an Asset Purchase Agreement (the Purchase Agreement ) with Parivid, LLC ( Parivid ), a data integration and analysis services provider to the Company, and S. Raguram, the principal owner and Chief Technology Officer of Parivid, pursuant to which the Company acquired patent rights, software, know-how and other intangible assets, and assumed certain specified liabilities of Parivid related to the acquired assets, for $2.5 million in cash paid at closing and up to $11.0 million in additional payments, which, if certain milestones are achieved, will be paid in a combination of cash and/or stock.

The milestone payments include (i) potential cash payments of no more than $2.0 million if certain milestones are achieved within two years from the date of the Purchase Agreement and (ii) the issuance of up to $9.0 million of the Company s common stock to Parivid if certain other milestones are achieved within fifteen years of the date of the Purchase Agreement. In addition, upon the completion and satisfaction of those milestones that trigger the issuance of shares of the Company s common stock, the Company has granted Parivid certain registration rights under the Securities Act of 1933, as amended, with respect to such shares. The Company also entered into an employment agreement with S. Raguram.

As part of the acquisition of assets from Parivid, two previous collaboration agreements that had been in place with Parivid were terminated. S. Raguram is the brother of a member of the Company s Board of Directors, who received no consideration in connection with the execution of the Purchase Agreement.

The Company has recorded a total purchase price of $4.5 million that includes $2.5 million paid in cash at the closing and $2.0 million in milestone payments which are probable. The total purchase price was allocated to the assets acquired based on their estimated relative fair values at the date of acquisition. The fair values of the acquired assets were determined using a combination of the income approach and the comparative business valuation method. At the date of acquisition, the Company recorded an acquired in-process research and development charge of $0.7 million, which is included in research and development expense in the consolidated statement of operation for the nine months ended September 30, 2007.

As of September 30, 2007, intangible assets, net of accumulated amortization, are as follows (in thousands):

| | | September 30, 2007 | |
|---|---|---|---|
| | Estimated Life | Gross Carrying Amount | Accumulated Amortization |
| Core technology | 12 years | $ 3,593 | $ (134) |
| Non-compete agreement | 2 years | 170 | (38) |
| Total intangible assets | | $ 3,763 | $ (172) |

Amortization is computed using the straight-line method over the useful lives of the respective intangible assets. Amortization expense was $0.1 million and $0.2 million during the three and nine months ended September 30, 2007, respectively.

The Company expects to incur amortization expense ranging from $0.3 million to $0.4 million per year for each of the next five years.

## 4. Commitments and Contingencies

***Capital Lease***

In September 2007, the Company borrowed an additional $1.7 million under its Master Lease Agreement (the Agreement ) with General Electric Capital Corporation ( GECC ) and executed an equipment schedule for laboratory, computer and office equipment. As of September 30, 2007, the Company had drawn a total of $9.4 million against the Agreement. Borrowings under the Agreement are payable over a 54-month period at an effective annual interest rate of 9.36%. In accordance with the Agreement, should the effective corporate income tax rate for calendar-year taxpayers increase above 35%, GECC will have the right to increase rent payments by requiring payment of a single additional sum, calculated in accordance with the Agreement. The Agreement also provides the Company an early purchase option after 48 months at a predetermined fair market value, which the Company intends to exercise. Under the Agreement, if any material adverse change in the Company or its business occurs, the total unpaid principal would become immediately due and payable. To date, there have been no events of default. As of September 30, 2007, the Company had approximately $8.1 million in borrowings outstanding under the Agreement.

## 5. Collaboration Agreements

***2003 Sandoz Collaboration***

In November 2003, the Company entered into a collaboration and license agreement (the 2003 Sandoz Collaboration ) with Sandoz N.V. and Sandoz Inc. to jointly develop and commercialize M-Enoxaparin, a generic version of Lovenox®, a low molecular weight heparin. Sandoz N.V. later assigned its rights and obligations under the 2003 Sandoz Collaboration to Sandoz AG. Sandoz AG and Sandoz Inc. are collectively referred to as Sandoz. Under the 2003 Sandoz Collaboration, the Company granted Sandoz the exclusive right to manufacture, distribute and sell M-Enoxaparin in the United States. The Company agreed to provide development and related services on a commercially reasonable best-efforts basis, which includes developing a manufacturing process to make M-Enoxaparin, scaling up the process, contributing to the preparation of an Abbreviated New Drug Application, or ANDA, in Sandoz name to be filed with the Food & Drug Administration, or FDA, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee which is

responsible for overseeing development, legal and commercial activities and approves the annual collaboration plan. Sandoz is responsible for commercialization activities and will exclusively distribute and market the product.

As compensation under the 2003 Sandoz Collaboration, the Company received a $588,000 non-refundable up-front payment as reimbursement for certain specified vendor costs that were incurred prior to the effective date of the 2003 Sandoz Collaboration. The Company is paid at cost for external costs incurred for development and related activities and is paid for full time equivalents ( FTEs ) performing development and related services. In addition, Sandoz will, in the event there are no third party competitors marketing a Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration) share profits with the Company. Alternatively, in certain circumstances, if there are third party competitors marketing a Lovenox-Equivalent Product, Sandoz will pay royalties to the Company on net sales of injectable M-Enoxaparin. If certain milestones are achieved with respect to injectable M-Enoxaparin under certain circumstances, Sandoz will make certain milestone payments to the Company, which would reach $55 million if all such milestones are achieved. A portion of the development expenses and certain legal expenses, which in the aggregate have exceeded a specified amount, will be offset against profit-sharing amounts, royalties and milestone payments. Sandoz also may offset a portion of any product liability costs and certain other expenses arising from patent litigation against any profit-sharing amounts, royalties and milestone payments. The Company has not earned any milestones, royalties or profit-share to date.

The Company recognizes the $588,000 non-refundable up-front payment as revenue on a straight line basis over the estimated M-Enoxaparin development period. In June 2007, the Company revised its original estimate of the development period from 4 years to 4.4 years due to a change in the projected timing of regulatory activities. The change in estimate is not material to the Company s net loss or net loss per share for the three and nine months ended September 30, 2007. The Company recognized revenue relating to this up-front payment of approximately $18,000 and $86,000 for the three and nine months ended September 30, 2007, respectively.

The Company recognizes revenue from FTE services and revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenues from external development costs are recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third party vendors for such development and related services, except with respect to any amounts due Sandoz for manufacturing raw material purchases, which are recorded on a net basis as an offset to the related development expense pursuant to the provisions of EITF No. 02-16, *Accounting by a Customer (Including a Reseller) for Certain Consideration Received from a Vendor*. There were no such manufacturing raw material purchases in the nine months ended September 30, 2007 and $1.1 million and $2.2 million during the three and nine months ended September 30, 2006, respectively.

***2006 Sandoz Collaboration***

In July 2006, the Company entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement, each with Novartis Pharma AG, and a Memorandum of Understanding (the MOU ) with Sandoz AG, an affiliate of Novartis Pharma AG. On June 13, 2007, the Company and Sandoz AG executed a definitive collaboration and license agreement (the Definitive Agreement ), which superseded the MOU. Together, this series of agreements is referred to as the 2006 Sandoz Collaboration.

Pursuant to the terms of the Stock Purchase Agreement, the Company sold 4,708,679 shares of common stock to Novartis Pharma AG at a per share price of $15.93 (the closing price of the Company s common stock on the NASDAQ was $13.05 on the date of the Stock Purchase Agreement) for an aggregate purchase price of $75.0 million, resulting in a paid premium of $13.6 million. The Company recognizes revenue from the $13.6 million paid premium on a straight-line basis over the estimated development period of approximately six years beginning in June 2007. Under the 2006 Sandoz Collaboration, the Company and Sandoz AG expanded the M-Enoxaparin geographic markets covered by the 2003 Sandoz Collaboration to include the European Union and further agreed to exclusively collaborate on the development and commercialization of three other follow-on and complex generic products for sale in specified regions of the world. Each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all medical indications in the

relevant regions. The Company has agreed to provide development and related services on a commercially reasonable best-efforts basis, which includes developing a manufacturing process to make the products, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and approves the annual collaboration plan. Sandoz AG is responsible for commercialization activities and will exclusively distribute and market the products.

The term of the Definitive Agreement extends throughout the development and commercialization of the products until the last sale of the products, unless earlier terminated by either party pursuant to the provisions of the Definitive Agreement. Sandoz AG has agreed to indemnify the Company for various claims, and a certain portion of such costs may be offset against certain future payments received by the Company.

Costs, including development costs and the cost of clinical studies, will be borne by the parties in varying proportions, depending on the type of expense and the related product. All commercialization responsibilities and costs will be borne by Sandoz. Under the 2006 Sandoz Collaboration, the Company is paid at cost for any external costs incurred in the development of products where development activities are funded solely by Sandoz AG, or partly in proportion where development costs are shared between the

Company and Sandoz AG. The Company also is paid for FTEs performing development services where development activities are funded solely by Sandoz AG, or partly by proportion where development costs are shared between the Company and Sandoz AG. The parties will share profits in varying proportions, depending on the product. The Company is eligible to receive up to $188.0 million in milestone payments if all milestones are achieved for the four product candidates. None of these payments, once received, are refundable and there are no general rights of return in the arrangement.

The Company recognizes revenue from FTE services and revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs are recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third party vendors for such development and related services, except with respect to any amounts due Sandoz for shared development costs, which are recorded on a net basis.

## 6. Stock-Based Compensation

Total compensation cost for all share-based payment arrangements including stock options, restricted stock and the Company s Employee Stock Purchase Plan ( ESPP ) for the three months ended September 30, 2007 and 2006 was $2.7 million and $2.0 million, respectively. Total compensation cost for all share-based payment arrangements for the nine months ended September 30, 2007 and 2006 was $9.6 million and $7.4 million, respectively.

The Company recorded stock-based compensation of $1.7 million and $1.4 million, and $5.1 million and $4.5 million related to outstanding employee stock option grants and the ESPP during the three and nine months ended September 30, 2007 and 2006, respectively. The Company recorded stock-based compensation of $2,100 and $32,000, and $5,600 and $0.2 million related to outstanding consultant stock option grants during the three and nine months ended September 30, 2007 and 2006, respectively. The weighted average grant date fair value of option awards granted to employees was calculated using the Black-Scholes-Merton option-pricing model and the assumptions in the following table. The weighted average grant date fair value of option awards granted during the three months ended September 30, 2007 and 2006 was $7.34 and $10.77 per option, respectively. The weighted average grant date fair value of option awards granted during the nine months ended September 30, 2007 and 2006 was $8.38 and $11.58 per option, respectively.

| | Three Months Ended September 30, 2007 | Three Months Ended September 30, 2006 | Nine Months Ended September 30, 2007 | Nine Months Ended September 30, 2006 |
|---|---|---|---|---|
| Expected volatility | 76% | 72% | 75% | 71% |
| Expected dividends | | | | |
| Expected term (in years) | 6 | 6 | 6 | 6 |
| Risk-free interest rate | 4.5% | 4.8% | 4.8% | 4.8% |

At September 30, 2007, the total unrecognized compensation costs related to nonvested employee stock option awards was $14.3 million, which is expected to be recognized over a weighted average period of 2.6 years. The unvested shares held by consultants have been and will be revalued using the Company s estimate of fair value at each balance sheet date pursuant to EITF 96-18.

In June 2007, the Company revised the implicit service period for certain performance-based restricted stock awards due to a change in the expected vesting date. As a result of this change in estimate, the Company s net loss was $1.1 million and $1.4 million less than had the estimate

remained unchanged for the three and nine months ended September 30, 2007, respectively. The impact of this change in estimate on the Company s net loss per share was not material. The Company recorded stock-based compensation expense of $1.0 million and $1.0 million related to outstanding restricted stock grants during the three months ended September 30, 2007 and 2006, respectively. The Company recorded stock-based compensation expense of $4.5 million and $2.8 million related to outstanding restricted stock grants during the nine months ended September 30, 2007 and 2006, respectively. As of September 30, 2007, there was $6.0 million of unrecognized compensation cost related to nonvested restricted stock arrangements, which is expected to be recognized over a weighted average period of 1.5 years.

During the nine months ended September 30, 2007, holders of options issued under the Company s stock plans exercised their right to acquire an aggregate of 82,536 shares of common stock. Additionally, the Company issued 42,689 shares of common stock to employees under the Company s ESPP during the nine months ended September 30, 2007.

## 7. Recently Issued Accounting Standards

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities,* or SFAS 159, which is effective for fiscal years beginning after November 15, 2007. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities

with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. The Company is currently analyzing the effect, if any, SFAS 159 will have on its consolidated financial position and results of operations.

In June 2007, the FASB issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3. EITF 07-3 requires that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. EITF 07-3 is effective for new contracts entered into during fiscal years beginning after December 15, 2007. The Company is currently analyzing the effect, if any, EITF 07-3 will have on its consolidated financial position and results of operations.

## 8. Subsequent Events

***Assignment of Sublease***

In July 2007, the Company evaluated its space needs and determined that additional office and laboratory space, which it had leased in September 2006, pursuant to a Sublease Agreement (the Sublease ) dated September, 2006 with Archemix Corp., as sublandlord ( Archemix ) but not yet occupied, was in excess of the Company s present requirements. Accordingly, in October 2007, the Company and Alnylam Pharmaceuticals, Inc. ( Alnylam ) executed an agreement pursuant to which Alnylam agreed to assume the Company s rights and obligations under the Sublease.

Under the terms of the Sublease, the Company had subleased from Archemix approximately 22,300 rentable square feet in Cambridge, Massachusetts which the Company had intended to use for office and laboratory space. The initial term of the Sublease was to expire on April 30, 2011 with an option to extend for an additional 48 month period, subject to certain termination rights granted to each of the Company and Archemix. Commencing on March 10, 2007, the Company began paying and expensing annual fixed rent of approximately $1.1 million, plus operating expenses. In connection with the execution of the Sublease, the Company issued a letter of credit in favor of Archemix in the amount of $2.9 million.

Under the agreement with Alnylam, Alnylam has agreed to pay the Company approximately $4.4 million (the Purchase Price ) to offset certain rent payments and fees paid by the Company to architects, contractors, brokers and other vendors engaged to build out the space. In consideration for the Purchase Price, Alnylam will assume all rights and obligations of the Company under a construction contract, an architect agreement and various permits and approvals. Alnylam will also receive, among other things, architectural drawings, construction plans and specifications, equipment and furniture. The effect of this transaction will be a reduction in the Company s property and equipment of approximately $3.7 million and a recovery of operating expenses of approximately $0.7 million. In addition, upon the cancellation of the letter of credit, $2.9 million will be to be reclassified from restricted cash to cash and cash equivalents.

***FDA Letter Regarding M- Enoxaparin ANDA***

On November 5, 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin is not approvable. The FDA s action letter indicated that the ANDA for M-Enoxaparin was not approvable in its current form because the application does not adequately address the potential for immunogenicity of the drug product. The FDA recommended in its letter that the Company and Sandoz meet with the Office of Generic Drugs to determine what additional information should be provided to adequately address this concern. Sandoz and the Company are working together to identify the additional information necessary to obtain approval of M-Enoxaparin.

Management has assessed the potential financial statement implications of this event and, based on its current estimates and plans, does not believe that any such changes in estimates materially affect the Company s financial statements for the three and nine months ended September 30, 2007 or any future period financial statements.

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

Our Management s Discussion and Analysis of Financial Condition and Results of Operations includes the identification of certain trends and other statements that may predict or anticipate future business or financial results. There are important factors that could cause our actual results to differ materially from those indicated. See Risk Factors in Item 1A. of Part II of this Quarterly Report on Form 10-Q.

**Business Overview**

We are a biotechnology company specializing in the detailed structural analysis of complex mixture drugs. We apply our technology to the development of generic versions of complex drug products as well as to the discovery and development of novel drugs. Through detailed analysis of the molecular structure of complex sugars and other complex mixtures, we believe our proprietary technology enables us to define specific sequences contained in complex drugs, including those structures that had previously not been described due to a lack of available technology. We apply our technology to the discovery and development of novel drugs by gaining a deeper understanding of the role of sugars in disease, such as the roles that complex sugars play in cellular function, disease and drug action. With our capabilities, we have developed a diversified pipeline of complex generic and novel drug candidates, as well as a novel drug discovery program.

Our business strategy is to apply our technology to develop generic versions of complex drugs, such as M-Enoxaparin and M356, to generate product revenue that we anticipate will contribute to funding our novel drug discovery and development programs. Over the long term, we expect to generate additional value by leveraging our understanding of sugars to create novel therapeutics, which potentially could address critical unmet medical needs in a wide range of disease areas, including oncology, cardiovascular disease, infectious disease, inflammation and immunology.

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox®, a widely prescribed low molecular weight heparin, or LMWH. In 2003, we formed a collaboration with Sandoz N.V. and Sandoz Inc., affiliates of Novartis AG, to jointly develop, manufacture and commercialize M-Enoxaparin in the U.S. Sandoz N.V. later assigned its rights and obligations to Sandoz AG, and Sandoz AG and Sandoz Inc. are referred to together as Sandoz. We refer to this collaboration as the 2003 Sandoz Collaboration .

In July 2006, we entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement with Novartis Pharma AG and a Memorandum of Understanding, or MOU, with Sandoz AG, an affiliate of Novartis Pharma AG. On June 13, 2007, we and Sandoz AG executed a definitive collaboration and license agreement, or the Definitive Agreement, which superseded the MOU. We refer to this series of agreements collectively as the 2006 Sandoz Collaboration. Under the 2006 Sandoz Collaboration, we expanded the geographic markets covered by the 2003 Sandoz Collaboration related to M-Enoxaparin to include the European Union and further agreed to exclusively collaborate on the development and commercialization of three other follow-on and complex generic products for sale in specified regions of the world. Each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all medical indications in the relevant regions.

Since our inception, we have incurred annual net losses. As of September 30, 2007, we had an accumulated deficit of $180.1 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 plan to continue to evaluate possible acquisitions or licensing of rights to additional technologies, products or assets that fit within our growth strategy. Accordingly, we will need to generate significant revenues to achieve and then maintain profitability.

Since our inception, we have had no revenues from product sales. Our revenues have all been derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration and primarily consist of amounts earned by us for reimbursement by Sandoz of research and development services and development costs for certain programs. In June 2004, we completed an initial public offering of 6,152,500 shares of common stock, the net proceeds of which were $35.3 million after deducting underwriters discounts and expenses. In July 2005, we raised $122.3 million in a follow-on public offering, net of expenses, from the sale and issuance of 4,827,300 shares of our common stock. In September 2006, in connection with the 2006 Sandoz Collaboration, we sold 4,708,679 shares of common stock to Novartis Pharma AG for an aggregate purchase price of $75.0 million. To date, we have devoted substantially all of our capital resource expenditures 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 rapidly 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 successfully demonstrate to the FDA that M-Enoxaparin is therapeutically equivalent to Lovenox; meeting any other FDA requirements for marketing approval; successfully manufacturing

M-Enoxaparin in a consistent, cost-effective and reproducible manner and at a commercial scale; achieving a favorable outcome in any patent litigation with Sanofi-Aventis relating to enoxaparin, or a third party achieving a favorable outcome in the pending patent litigation with Sanofi-Aventis; and achieving market acceptance of M-Enoxaparin in the medical community and with third-party payors. Our success will also be impacted by the FDA s approval of other companies generic versions of Lovenox.

**Asset Purchase**

On April 20, 2007, we entered into an asset purchase agreement, or the Purchase Agreement, with Parivid, LLC, or Parivid, a provider of data integration and analysis services to us, and S. Raguram, the principal owner and Chief Technology Officer of Parivid, pursuant to which we acquired certain of the assets and assumed certain specified liabilities of Parivid related to the acquired assets, for $2.5 million in cash paid at closing and up to $11.0 million in additional payments if certain milestones are achieved that will be paid in a combination of cash and/or stock.

The contingent milestone payments to include (i) potential cash payments of no more than $2.0 million if certain milestones are achieved within two years from the date of the Purchase Agreement and (ii) the issuance of up to $9.0 million of our common stock to Parivid if certain other milestones are achieved within fifteen years of the date of the Purchase Agreement. In addition, upon the completion and satisfaction of those milestones that trigger the issuance of shares of our common stock, we granted Parivid certain registration rights under the Securities Act of 1933, as amended, with respect to such shares. We also entered into an employment agreement with S. Raguram pursuant to the terms of the Purchase Agreement.

As part of our acquisition of assets from Parivid, two previous collaboration agreements we had in place with Parivid were terminated. S. Raguram is the brother of Ram Sasisekharan, a member of our Board of Directors. Ram Sasisekharan received no consideration in connection with the execution of the Purchase Agreement. We recorded $1.0 million, $0.7 million and $1.0 million as research and development expense related to work performed by Parivid in the years ended December 31, 2006, 2005 and 2004, respectively.

**Recent Developments**

***Assignment of Sublease***

In July 2007, we evaluated our space needs and determined that additional office and laboratory space, which had been leased in September 2006 pursuant to a Sublease Agreement (the Sublease ) dated September, 2006 by and between us and Archemix Corp., as sublandlord ( Archemix ), but not yet occupied, was in excess of our present requirements. Accordingly, in October 2007, we executed an agreement with Alnylam Pharmaceuticals, Inc. ( Alnylam ) pursuant to which Alnylam agreed to assume our rights and obligations under the Sublease.

Under the terms of the Sublease, we subleased from Archemix approximately 22,300 rentable square feet in Cambridge, Massachusetts which we intended to use for office and laboratory space. The initial term of the Sublease was to expire on April 30, 2011 with an option to extend for an additional 48 month period, subject to certain termination rights granted to Archemix and to us. Commencing on March 10, 2007, we began paying annual fixed rent of approximately $1.1 million, plus operating expenses. In connection with the execution of the Sublease, we issued a letter of credit in favor of Archemix in the amount of $2.9 million.

Under the agreement with Alnylam, Alnylam has agreed to pay us approximately $4.4 million (the Purchase Price ) to offset certain rent payments and fees paid by us to architects, contractors, brokers and other vendors engaged to build out the space. In consideration for the Purchase Price, Alnylam will assume all of our rights and obligations under a construction contract, an architect agreement and various permits and approvals. Alnylam shall also receive, among other things, architectural drawings, construction plans and specifications, equipment and furniture. The effect of this transaction will be a reduction in our property and equipment of approximately $3.7 million and a recovery of operating expenses of approximately $0.7 million. In addition, upon the cancellation of the letter of credit, $2.9 million will be to be reclassified from restricted cash to cash and cash equivalents.

***FDA Letter Regarding M-Enoxaparin ANDA***

On November 5, 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin is not approvable. The FDA s action letter indicated that the ANDA for M-Enoxaparin was not approvable in its current form because the ANDA does not adequately address the potential for immunogenicity of the drug product. The FDA recommended in its letter that we and Sandoz meet with the Office of Generic Drugs to determine what additional information should be provided to adequately address this concern. We are working together with Sandoz to identify the additional information that is necessary to obtain approval of M-Enoxaparin.

**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, $49.9 million of revenue from our inception through September 30, 2007. This revenue was derived entirely from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration. 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 2003 Sandoz Collaboration and 2006 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. Due to the variability in the length of time necessary to develop a product, the uncertainties related to the estimated cost of the projects and ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the ultimate cost to bring our product candidates to market are not available.

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 to support the treatment of acute coronary syndromes, or ACS. Under our 2003 Sandoz Collaboration, we work with Sandoz exclusively to develop, manufacture and commercialize M-Enoxaparin in the U.S. and Sandoz is responsible for funding substantially all of the U.S.-related M-Enoxaparin development, regulatory, legal and commercialization costs. The total cost of development and commercialization, and the timing of M-Enoxaparin product launch, are subject to uncertainties relating to the development, regulatory approval and legal processes. In accordance with our 2003 Sandoz Collaboration, Sandoz submitted ANDAs in its name to the FDA for M-Enoxaparin in syringe and vial forms seeking approval to market M-Enoxaparin in the United States. Both ANDAs currently include a paragraph IV certification stating that Sanofi-Aventis patents listed in the Orange Book for Lovenox are, among other things, invalid and unenforceable.

The FDA is currently reviewing both M-Enoxaparin ANDAs, including our manufacturing data and technology and characterization methodology. In parallel, and in collaboration with Sandoz, we are focused on activities related to supporting the FDA s review of the ANDAs and preparing for the commercialization of M-Enoxaparin, if and when approved, by advancing manufacturing, supply chain, and sales and marketing objectives. On November 5, 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin is not approvable. The FDA s action letter indicated that the ANDA for M-Enoxaparin was not approvable in its current form because the ANDA does not adequately address the potential for immunogenicity of the drug product. The FDA recommended in its letter that we and Sandoz meet with the Office of Generic Drugs to determine what additional information should be provided to adequately address this concern. We are working together with Sandoz identify the the additional information that is necessary to obtain approval of M-Enoxaparin.

Our 2006 Sandoz Collaboration expanded our collaboration efforts related to M-Enoxaparin to include the European Union. Under the 2006 Sandoz Collaboration, we will share certain development, regulatory, legal and commercialization costs as well as a portion of the profits, if any.

M118

M118 is a novel anticoagulant drug that was rationally designed with the goal of providing improved clinical anticoagulant properties to support the treatment of patients diagnosed with ACS and stable angina. We believe that M118 has the potential to provide baseline anticoagulant therapy to treat coronary artery disease and patients with ACS or stable angina who require invasive treatment, as well as those ACS patients who are medically managed, or do not require invasive treatment. M118 is designed to be a reversible and monitorable anticoagulant that can be administered intravenously or subcutaneously and have a pharmacokinetic profile similar to other LMWHs. We believe that these properties of M118 have the potential to provide greater flexibility than other therapies presently used to treat patients diagnosed with ACS and stable angina.

In July 2006, we filed our Investigational New Drug Application, or IND, with the FDA for our M118 intravenous injection formulation, and in October 2006 began Phase I clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. In

October 2007, we began a Phase IIa clinical trial to evaluate the feasibility of utilizing M118 intravenous injection formulation as an anticoagulant in patients with stable coronary artery disease undergoing percutaneous coronary intervention. In April 2007, we filed our IND for our M118 subcutaneous formulation, and in May 2007 began Phase I clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile.

M356

M356 is targeted to be a technology-enabled generic version of Copaxone®, a complex drug consisting of a mixture of polypeptide chains. Copaxone is indicated for reduction of the frequency of relapses in patients with Relapse-Remitting Multiple Sclerosis. Multiple sclerosis is a chronic disease of the central nervous system characterized by inflammation and neurodegeneration. In North America, Copaxone is marketed through Teva Neuroscience LLC, a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., and distributed by Sanofi-Aventis. Teva and Sanofi-Aventis have an additional collaborative arrangement for the marketing of Copaxone in Europe and other markets, under which Copaxone is either co-promoted with Teva or is marketed solely by Sanofi-Aventis. Under the Definitive Agreement, we and Sandoz jointly develop, manufacture and commercialize M356. We are responsible for funding substantially all of the U.S.-related M356 development costs, with Sandoz responsible for legal and commercialization costs. Outside of the U.S., we and Sandoz share equally the development costs, with Sandoz responsible for commercialization and legal costs.

Glycoproteins

Our glycoprotein program is focused on extending our technology for the analysis of complex sugars to the analysis of glycoproteins. The goal of the program is to facilitate the development of follow-on versions of major marketed glycoprotein drugs. In addition, we believe we can assist pharmaceutical and biotechnology companies in developing improved versions of their branded glycoprotein products by analyzing and modifying the sugar structures contained in those products.

Glycoprotein drugs, which include drugs like erythropoietin, blood clotting factors and interferon beta, exist as complex mixtures and contain various modifications, including branched sugars that vary from molecule to molecule, that affect their key clinical properties. Many of these products have not been thoroughly characterized to date given their complexity and the inadequacies in standard analytic technology. This makes them attractive candidates for application of Momenta s characterization technology.

Under our 2006 Sandoz Collaboration, we are currently applying our technology to develop two follow-on proteins in partnership with Sandoz AG. We refer to these two product candidates as M178 and M249.

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. In September 2005, Eisai Inc., a U.S. pharmaceutical subsidiary of Eisai Co. Ltd., obtained U.S. promotion rights to Fragmin from Pfizer Inc. Fragmin is marketed by Pfizer in Europe and by Kissei Pharmaceutical Co., Ltd. in Japan. Through our technology, we believe we have the ability to analyze Fragmin and develop a generic product that can be demonstrated to be therapeutically equivalent to Fragmin. Our M-Dalteparin program has been put on hold in light of other more commercially attractive

opportunities.

*Discovery Program*

We are also applying our analytical capabilities to drug discovery. Our 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 the area of cancer, where we are seeking to discover sugar sequences with anti-cancer properties for development as therapeutics, and we are advancing an oncology product candidate that is in the discovery phase. 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, enabling us to discover novel sugar therapeutics, as well as to discover new disease mechanisms that can be targeted with other small molecule and biologic 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 and other general expenses.

**Results of Operations**

***Three Months Ended September 30, 2007 and 2006***

***Revenue***

Revenues for the three months ended September 30, 2007 and 2006 were $5.1 million and $4.1 million, respectively. Revenues for the three months ended September 30, 2007 consist of (i) amounts earned by us under our 2003 Sandoz Collaboration for reimbursement of research and development services, reimbursement of development costs and amortization of the initial payment received, and (ii) amounts earned by us under our 2006 Sandoz Collaboration for amortization of the equity premium, reimbursement of research and development services and reimbursement of development costs. Revenues for the three months ended September 30, 2006 consist of amounts earned by us for reimbursement of research and development services, reimbursement of development costs and amortization of the initial payment received under our 2003 Sandoz Collaboration. The increase in revenues is a result of the increase in reimbursable development costs and the amortization of the equity premium related to the 2006 Sandoz Collaboration.

***Research and Development***

The following table summarizes the primary components of our research and development expense for our principal research and development programs for the three months ended September 30, 2007 and 2006:

| | (in thousands) | |
|---|---|---|
| **Research and Development Program** | **2007** | **2006** |
| Development programs | $ 18,371 | $ 9,077 |
| Discovery programs | 1,151 | 1,167 |
| Other research | 25 | 440 |
| Total research and development expense | $ 19,547 | $ 10,684 |

Research and development expense for the three months ended September 30, 2007 was $19.5 million compared to $10.7 million during the three months ended September 30, 2006. The increase of $8.8 million from 2006 to 2007 resulted primarily from an increase of $3.7 million in manufacturing costs and research conducted by third parties, $2.7 million in clinical trial costs and $2.2 million in personnel and related costs due to increased headcount.

The increase in expenditures on our development programs of $9.3 million was primarily related to increases in the expenses of our M356, M118, M-Enoxaparin and glycoprotein programs. Our M356 program manufacturing and research costs have increased as we advance the program. M118 clinical costs have increased as we have progressed from preclinical to Phase 1 studies. M-Enoxaparin manufacturing costs have increased as we prepare for commercial launch. Our glycoprotein program expenditures have increased as we devote additional headcount resources to facilitate the development of follow-on versions of glycoprotein drugs.

The discovery program expenditures include a decrease of approximately $0.5 million due to the termination of the drug delivery program in late 2006, offset by increased disease biology program expenditures of approximately $0.5 million representing additional resources dedicated to applying our analytical capabilities to drug discovery.

The decrease in other research expense of $0.4 million was primarily due to a decrease in headcount and headcount related costs relating to general technology development and support activities as resources are allocated to development programs.

***General and Administrative***

General and administrative expense for the three months ended September 30, 2007 was $6.3 million compared to $7.2 million during the three months ended September 30, 2006. The decrease of $0.9 million was primarily due to a decrease of $1.0 million in professional fees due to a reduction in legal activities.

***Interest Income and Expense***

Interest income of $2.0 million for the three months ended September 30, 2007 was consistent with the $2.0 million in interest income for the three months ended September 30, 2006, as the average investment balances were comparable period to period. Interest expense of $0.2 million for the three months ended September 30, 2007 was unchanged compared to the three months ended September 30, 2006.

***Nine Months Ended September 30, 2007 and 2006***

***Revenue***

Revenues for the nine months ended September 30, 2007 and 2006 were $11.6 million and $12.0 million, respectively. Revenues for the nine months ended September 30, 2007 consist of (i) amounts earned by us under our 2003 Sandoz Collaboration for

reimbursement of research and development services, reimbursement of development costs and amortization of the initial payment received and (ii) amounts earned by us under our 2006 Sandoz Collaboration for amortization of the equity premium, reimbursement of research and development services and reimbursement of development costs. Revenues for the nine months ended September 30, 2006 consist of amounts earned by us for reimbursement of research and development services, reimbursement of development costs and amortization of the initial payment received under our 2003 Sandoz Collaboration. The decrease in revenues is a result of the decrease in reimbursable development activities for M-Enoxaparin. As we prepare for the launch of M-Enoxaparin, development activities are decreasing while commercial activities are increasing.

***Research and Development***

The following table summarizes the primary components of our research and development expense for our principal research and development programs for the nine months ended September 30, 2007 and 2006:

| | (in thousands) | |
|---|---|---|
| **Research and Development Program** | **2007** | **2006** |
| Development programs | $ 46,958 | $ 28,564 |
| Discovery programs | 3,170 | 3,971 |
| Other research | 179 | 1,065 |
| Total research and development expense | $ 50,307 | $ 33,600 |

Research and development expense for the nine months ended September 30, 2007 was $50.3 million compared to $33.6 million during the nine months ended September 30, 2006. The increase of $16.7 million from 2006 to 2007 principally resulted from an increase of $5.3 million in manufacturing and research provided by third parties due to increased expenditures for our M356 and M118 programs, $5.3 million in personnel and related costs due to increased headcount, $3.8 million in clinical trial costs for our M118 program, $1.6 million in facilities costs and a $0.7 million in-process research and development charge related to the Parivid asset purchase.

The increase in expenditures on our development programs of $18.4 million was primarily related to the expenses of our M356, M118 and glycoprotein programs. Our M356 program manufacturing and research costs have increased as we advance the program. M118 clinical costs have increased as we have progressed from preclinical to Phase 1 studies. Our glycoprotein program expenditures have increased as we devote additional headcount resources to facilitate the development of follow-on versions of glycoprotein drugs.

The decrease in our discovery program expenditures of $0.8 million was the result of decreased drug delivery program expenditures of $2.0 million due to the termination of the program in late 2006, offset by increased disease biology program expenditures of $1.2 million representing additional resources dedicated to applying our analytical capabilities to drug discovery.

The decrease in other research expense of $0.9 million was primarily due to a decrease in headcount and headcount related costs relating to general technology development and support activities as resources are allocated to development programs.

***General and Administrative***

General and administrative expense for the nine months ended September 30, 2007 was $22.0 million compared to $19.3 million during the nine months ended September 30, 2006. The increase of $2.7 million was primarily due to an increase of $1.3 million in personnel and related costs due to increased headcount and $1.7 million in stock-based compensation, offset by a decrease of $0.3 million in professional fees due to a reduction in legal activities.

***Interest Income and Expense***

Interest income increased to approximately $6.7 million for the nine months ended September 30, 2007 from approximately $5.3 million for the nine months ended September 30, 2006, primarily due to higher average investment balances as a result of the proceeds from issuance of common stock to Novartis Pharma AG in September 2006. Interest expense increased to approximately $0.6 million for the nine months ended September 30, 2007 from approximately $0.3 million for the nine months ended September 30, 2006, due to additional amounts drawn from our equipment line of credit during 2006 and 2007.

**Liquidity and Capital Resources**

We have financed our operations since inception primarily through the sale of equity securities, payments from our 2003 Sandoz Collaboration and borrowings from our lines of credit and capital lease obligations.

At September 30, 2007, we had $141.3 million in cash, cash equivalents and marketable securities. In addition, we held $4.7 million in restricted cash that serves as collateral for letters of credit related to our facility leases. During the nine months ended September 30, 2007 and 2006, our operating activities used $47.2 million and $13.9 million, respectively. The use of cash for

operating activities generally approximates our net loss adjusted for non-cash items and changes in operating assets and liabilities. Our net losses have increased year over year as we increase our headcount and continue to develop our product candidates. For the nine months ended September 30, 2007, our net loss adjusted for non-cash items was $46.5 million. In addition, the net change in our operating assets and liabilities used $0.7 million and resulted from: an increase in accounts receivable of $1.5 million due to timing of cash receipts from our sole customer; a decrease in deferred revenue of $0.7 million representing amortization of the $13.6 million equity investment premium paid by Novartis in connection with the 2006 Sandoz Collaboration; an increase in prepaid expenses and other current assets of $0.5 million related to payments made to vendors in advance of M118 clinical trial activities; and a net increase in accounts payable and accrued expenses of $1.7 million resulting from increased manufacturing and research costs for our programs.

For the nine months ended September 30, 2006, our net loss adjusted for non-cash items was $27.2 million. In addition, the net change in our operating assets and liabilities provided $13.3 million, primarily due to an increase in deferred revenue of $13.4 million relating to the equity investment premium paid by Novartis.

Investing activities for the nine months ended September 30, 2007 provided $40.4 million while investing activities for the nine months ended September 30, 2006 used $6.0 million. In the first nine months of 2007, we used $195.2 million of cash to purchase marketable securities and had $246.3 million in maturities of marketable securities. In the first nine months of 2006, we used $141.1 million of cash to purchase marketable securities and had $141.9 million in maturities of marketable securities. In the first nine months of 2007 and 2006, we used $8.2 million and $6.8 million, respectively, to purchase equipment and leasehold improvements. In the first nine months of 2007, we paid $2.5 million in connection with entering into the Purchase Agreement with Parivid.

Net cash provided by financing activities for the nine months ended September 30, 2007 was $2.8 million. We had borrowings of $3.9 million on an equipment lease agreement entered into in 2005 and received proceeds of $0.7 million from stock option exercises and purchases of common shares through our Employee Stock Purchase Plan. These proceeds were offset by principal payments of $1.4 million on our line of credit and lease agreement obligations and $0.4 million on financed leasehold improvements related to our corporate facility. Net cash provided by financing activities for the nine months ended September 30, 2006 was $66.2 million. We received net proceeds of $74.9 million from the sale of 4,708,679 shares of common stock to Novartis Pharma AG, of which $13.5 million was included in deferred revenue in our consolidated balance sheet as of September 30, 2006. Additionally, we had borrowings of $1.5 million on an equipment lease agreement entered into in 2005, received $3.2 million in financing from our landlord for leasehold improvements related to our corporate facility, and received proceeds of $1.1 million from stock option exercises and purchases of common shares through our Employee Stock Purchase Plan, offset by principal payments of $0.9 million on our line of credit and lease agreement obligations and payments of $0.1 million on financed leasehold improvements.

We anticipate that our current cash, cash equivalents and short-term investments will be sufficient to fund our operations through at least 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.

**Contractual Obligations**

Our major outstanding contractual obligations relate to license maintenance obligations, short and long-term line of credit obligations and capital and operating lease obligations. Except for obligations related to the Sublease, which were assigned pursuant to the October 31, 2007 agreement disclosed in footnote 8 to the financial statements, the disclosures relating to our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2006 have not materially changed since we filed that report.

**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 ongoing basis, we evaluate our estimates and judgments, including those related to revenue, accrued expenses and certain equity instruments. Prior to the initial public offering of our stock, 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. Payments 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. When we are required to defer revenue, the period over which such revenue is recognized is based on estimates by management and may change over the course of the performance period. At the inception of a collaboration agreement, we estimate the term of our performance obligation based on our development plans and our estimate of the regulatory review period. The development plans generally include designing a manufacturing process to make the drug product, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale and related development of intellectual property. Each reporting period we reassess our remaining performance obligations under the applicable collaboration arrangement by considering the time period over which any remaining development and related services to be provided prior to obtaining regulatory approval are expected to be completed. Changes in our estimate could occur due to changes in our development plans or due to changes in regulatory or legal requirements. We have deferred upfront payments of $0.6 million and $13.6 million in connection with our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, respectively. Such upfront payments are being recognized over our estimated period of performance obligation, which is approximately four and a half and six years, respectively, from the applicable collaboration inception date. During the three months ended June 30, 2007, we revised our original estimate of the development period under the 2003 Sandoz Collaboration agreement due to a change in the projected timing of certain activities required for the completion of the FDA s review of the ANDA for M-Enoxaparin. The change in estimate did not have a material impact on the Company s net loss or net loss per share for the three and nine months ended September 30, 2007.

Revenues from milestone payments that represent the culmination of a separate earnings process are recorded when the milestone is achieved.

***Intangible Assets***

We have acquired intangible assets that we value and record. Those assets for which there are no alternative uses are expensed as acquired in-process research and development, and those that are specifically identified and have alternative future uses are capitalized. We use a discounted cash flow model to value intangible assets at acquisition. The discounted cash flow model requires assumptions about the timing and amount of future cash inflows and outflows, risk and the cost of capital. Each of these factors can significantly affect the value of the intangible asset. We review intangible assets for impairment on a periodic basis using an undiscounted net cash flows approach when impairment indicators arise. If the undiscounted cash flows of an intangible asset are less than the carrying value of an intangible asset, we would write down the intangible asset to the discounted cash flow value. Where we cannot identify cash flows for an individual asset, our review is applied at the lowest group level for which cash flows are identifiable.

***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 and in accordance with generally accepted accounting principles.

***Stock-Based Compensation***

We adopted Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), *Share Based Payment*, or SFAS 123R, effective January 1, 2006 under the modified prospective transition method. SFAS 123R requires the recognition of the fair value of stock-based compensation expense in our operations, and accordingly the adoption of SFAS No. 123R fair value method has had and will continue to have a significant impact on our results of operations, although it will have no impact on our overall financial position. Option valuation models require the input of highly subjective assumptions, including stock price volatility and expected term of an option. Changes in market price directly affect volatility and could cause future stock-based compensation expense to vary significantly in future reporting periods. The compensation cost for stock options and our Employee Stock Purchase Plan that has been incurred during the three and nine months ended September 30, 2007 is $1.7 million and $5.1 million, respectively. At September 30, 2007, the total unrecognized compensation cost related to non-vested stock options was $14.3 million. The cost is expected to be recognized over a weighted average period of 2.6 years.

Due to our limited historical share options exercise data and the characteristics of our share options, we follow the simplified method of estimating the expected term, as described in the U.S. Securities and Exchange Commission, or SEC, issued Staff Accounting Bulletin, *Share-Based Payments,* or SAB 107. The expected term is derived from the average midpoint between vesting and the contractual term. We update these assumptions on a quarterly basis to reflect recent historical data. Additionally, we are required to estimate forfeiture rates to estimate the number of shares that will not vest due to forfeiture to which the fair value is applied.

The value of our restricted stock awards is recognized as compensation cost in our consolidated statement of operations over each award s explicit or implicit service periods. We estimate an award s implicit service period based on our best estimate of the period over which an award s vesting conditions will be achieved. We reevaluate these estimates on a quarterly basis and will recognize any remaining unrecognized compensation as of the date of an estimate revision over the revised remaining implicit service period. In June 2007, the Company revised the implicit service period for certain performance-based restricted stock awards due to a change in the expected vesting date. As a result of this change in estimate, the Company s net loss for the nine months ended September 30, 2007 was $1.4 million less than had the estimate remained unchanged. The impact of this change in estimate on the Company s net loss per share was not material. At September 30, 2007, the total unrecognized compensation cost related to non-vested restricted stock awards was $6.0 million. The costs are expected to be recognized over a weighted-average period of 1.5 years.

**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, 2007, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. While our cash and investment balances have increased as a result of our initial and follow-on public offerings, 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, 2007. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, 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 of 1934 is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act of 1934 is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. 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, 2007, 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, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

*Statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not based on historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, general and administrative expenses, research and development expenses, current and future development and manufacturing efforts, regulatory filings, clinical trial results and the sufficiency of our cash for future operations. Forward-looking statements can be identified by terminology such as anticipate, believe, could, could increase the likelihood, hope, target, project, goals, potential, predict, might, estimate, expect, intend, is planned, may, should, will, will enable, would be expected, look forward, may provide, would or similar terms, variations of such terms or the negative of those terms.*

*We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.*

The following discussion includes five revised risk factors *( If we fail to obtain approval for and commercialize our most advanced product candidate, M-Enoxaparin, we may have to curtall our product development programs and our business would be materially harmed, Patent litigation with Sanoft-Aventis, the innovator of Lovenox, may cause delays and additional expense in the commercialization of M-Enoxaparin. If we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, our business would be materially harmed, which could include without limitation the curtailment of our other development programs, 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, If we are not able to obtain regulatory approval for commercial sale of our generic product candidates as therapeutic equivalents to their corresponding reference listed drugs, including M-Enoxaparin, our future results of operations will be adversely affected, and Our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration are important to our business. If Sandoz fails to adequately perform under either collaboration, or we or Sandoz terminate all or a portion of either collaboration, the development and commercialization of some of our drug candidates, including injectable enoxaparin, would be delayed or terminated and our business would be adversely affected. )* that reflect developments subsequent to the discussion of risk factors included in our most recent Annual Report on Form 10-K.

**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, 2007, our accumulated deficit was approximately $180.1 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 successfully 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: 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 2003 Sandoz Collaboration, Sandoz submitted an ANDA to the FDA on August 29, 2005 seeking approval 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 an NDA. On November 5, 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin is not approvable. The FDA recommended in its letter that we and Sandoz meet with the Office of Generic Drugs to determine what additional information should be provided to adequately address this concern. If we are unable to satisfactorily demonstrate therapeutic equivalence, if the FDA disagrees with our characterization approach or does not agree that M-Enoxaparin is equivalent to Lovenox, if we fail to resolve questions raised in the FDA s correspondence regarding the M-Enoxaparin ANDA or if we otherwise fail to meet FDA requirements for the 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.

***Patent litigation with Sanofi-Aventis, the innovator of Lovenox, may cause delays and additional expense in the commercialization of M-Enoxaparin. If we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, our business would be materially harmed, which could include without limitation the curtailment of our other development programs.***

Companies that produce branded pharmaceutical products for which there are unexpired patents listed in the FDA s listing of approved drug products, the Orange Book, often bring patent infringement litigation against applicants seeking FDA approval to manufacture and market generic forms of the branded products before patent expiration. Litigation against Sandoz, us or others with respect to Lovenox may cause delays and additional expense in the commercialization of M-Enoxaparin.

Currently, Sanofi-Aventis has two listed patents for Lovenox in the Orange Book, U.S. Patent No. 5,389,618, or the 618 Patent, and Reissue Patent No. 38,743, or the RE 743 Patent. Sanofi-Aventis has reported that the claims of the 618 Patent are identical or substantially identical to the corresponding claims of the RE 743 Patent. According to Sanofi-Aventis, by operation of law, the 618 Patent ceases to exist and has been replaced by the RE 743 Patent. According to the Orange Book, the RE 743 Patent expires February 14, 2012.

Sanofi-Aventis has brought lawsuits for patent infringement; one against Amphastar Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc., and two separate patent infringement lawsuits against Sandoz.

*Amphastar/Teva Patent Infringement Lawsuit*

In September 2003, prior to issuance of the RE 743 Patent, Sanofi-Aventis announced that it received individual notices from Amphastar and Teva indicating that each had submitted with the FDA its own ANDA with a paragraph IV certification for enoxaparin. Sanofi-Aventis sued Amphastar and Teva for patent infringement, and in response Amphastar and Teva asserted claims of non-infringement, invalidity and/or unenforceability of the 618 Patent, as well as various counterclaims, and sought related declaratory judgment relief against Sanofi-Aventis. In September 2005, Amphastar and Teva each subsequently amended its own ANDA to include a second paragraph IV certification for the RE 743 Patent.

In June 2005, the District Court granted summary judgment in the Amphastar/Teva case, finding that the RE 743 Patent was unenforceable due to Aventis inequitable conduct before the United States Patent and Trademark Office, or USPTO. Thereafter, Sanofi-Aventis appealed the decision to the U.S. Court of Appeals for the Federal Circuit, or the Court of Appeals. On April 10, 2006, the Court of Appeals determined that, although there were no issues of material fact with respect to the materiality of certain information withheld from the USPTO, there remained genuine issues of material fact regarding the intent to deceive the USPTO. Accordingly, the Court of Appeals reversed the District Court s ruling and remanded the case to the District Court for further proceedings consistent with the Court of Appeals decision. The District Court held a bench trial in December 2006 focused only on inequitable conduct. In February 2007, the District Court ruled in favor of Amphastar and Teva holding both the 618 Patent and the RE 743 Patent unenforceable by virtue of inequitable conduct before the USPTO. Sanofi-Aventis appealed this ruling and the appeal is currently pending. If Sanofi-Aventis is successful in its appeal, all other remaining issues regarding invalidity, non-infringement and unenforceability could be subsequently tried by the District Court.

*Sandoz Patent Infringement Lawsuit*

In August 2005, Sandoz filed an ANDA with the FDA to obtain approval for the commercial manufacture, use and sale of the syringe formulation of enoxaparin. In 2006, Sandoz amended its ANDA by filing with the FDA a paragraph IV certification, stating, among other things, that the 618 Patent and RE 743 Patent are invalid and unenforceable. Sanofi-Aventis brought a patent infringement suit against Sandoz in August 2006. In response to Sanofi-Aventis lawsuit, Sandoz has moved for summary judgment of unenforceability of the 618 Patent and RE 743 Patent based upon the District Court decision in the Amphastar/Teva case, and the District Court has stayed the case against Sandoz until March 2008.

In December 2006, Sandoz filed an ANDA with the FDA to obtain approval for the commercial manufacture, use and sale of the vial formulation of enoxaparin and included a paragraph IV certification, stating, among other things, that the 618 Patent and RE 743 Patent are invalid and unenforceable. Sanofi-Aventis brought a patent infringement suit against Sandoz in September 2007. Sandoz has moved to dismiss the suit based upon the District Court decision in the Amphastar/Teva case, and the District Court has stayed the case against Sandoz until March 2008.

Continuing litigation could delay or prevent the introduction of M-Enoxaparin and Sanofi-Aventis efforts to litigate against potential generic challengers to enforce its intellectual property related to Lovenox may not be limited to enforcement of the RE 743 Patent. Pharmaceutical companies also frequently sue generic challengers over potential infringement of patents that are not listed in the Orange Book. Presently, we are not aware of any litigation relating to non-Orange Book patents, but it is possible that Sanofi-Aventis will initiate such litigation against us, Sandoz, Teva, Amphastar, or others in the future. If Sanofi-Aventis were to initiate litigation relating to a non-Orange Book patents, this litigation could significantly delay, impair or prevent our ability to commercialize M-Enoxaparin and our business would be materially harmed.

Under our 2003 Sandoz Collaboration, in 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 could decide to market M-Enoxaparin prior to final resolution of either the Teva and Amphastar or Sandoz litigation matters, which could result in significant damages, including possibly treble damages, in the event Sanofi-Aventis is successful in either patent litigation case. Although Sandoz has agreed to indemnify us for patent liability damages, Sandoz has the right 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.

Litigation involves many risks and uncertainties, and there is no assurance that Amphastar, Teva, Sandoz or we will prevail in any lawsuit with Sanofi-Aventis. In addition, Sanofi-Aventis has significant resources and any 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 other product development programs and our business would be materially harmed.

***If other generic versions of enoxaparin are approved and successfully commercialized, our business would suffer.***

In March 2003, Amphastar and Teva each submitted ANDAs for generic versions of Lovenox with the FDA. In addition, other third parties, including without limitation Sanofi-Aventis, may seek approval to market generic versions of Lovenox in the United States. If a competitor obtains FDA approval or obtains licenses from Sanofi-Aventis to market an authorized generic, the resulting financial returns to us would be materially adversely affected. Under these circumstances, we may not gain any competitive advantage and the resulting market price for our M-Enoxaparin product may be lower, we may be delayed from commercial launch or we may not be able to launch our product at all. Also, we may never achieve significant market share for M-Enoxaparin if one or more third parties markets generic versions of Lovenox. Under the Hatch-Waxman Act, any developer of a generic drug that is first to have its ANDA accepted for review by the FDA, and whose submission includes a paragraph IV certification, is eligible to receive a 180-day period of generic market exclusivity. Sandoz was not the first applicant to file an enoxaparin ANDA with a paragraph IV certification, so we will be forced to wait until the expiration of Teva and/or Amphastar s exclusivity period before the FDA will be able to finally approve our application. As a result, Teva and/or Amphastar may have the opportunity to establish long term supply agreements with institutional customers before we can enter the market, which would hinder our ability to penetrate the market for generic enoxaparin products

The 2003 Sandoz Collaboration contains terms which specify the sharing of commercial returns of M-Enoxaparin between us and Sandoz. Under circumstances when one or more third parties successfully commercialize a generic version of Lovenox, significantly less favorable economic terms would be triggered under our collaboration with Sandoz. Consequently, if other generic versions of Lovenox are approved and commercialized, our revenues for M-Enoxaparin would be reduced and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, would suffer.

***If other generic versions of our generic and novel drug products are approved and successfully commercialized, our business would suffer.***

We expect that certain of our generic product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. 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 this happens, or as branded manufacturers launch authorized 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 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 and M356, may be based on new technologies that have not previously been formally reviewed or accepted by the FDA or other regulatory authorities. It is possible that the FDA s review and acceptance of our technologies 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 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 raw materials, manufacture the drug substance, produce the final drug product and provide certain analytical

services with respect to M-Enoxaparin. We or our third party contractors may have difficulty meeting FDA manufacturing requirements, including but not limited to, reproducibility, validation and scale-up, and continued compliance with current good manufacturing practices requirements. In addition, we or our third party contractors may have difficulty producing M-Enoxaparin in the quantities necessary to meet anticipated market demand. 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.

***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 composed 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 impair our ability to develop improved, next-generation or follow-on versions of existing products. 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 key customer arrangements, sales of our products, and therefore revenues, would decline.***

Generic pharmaceutical products are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. As enoxaparin is primarily a hospital-based product, we expect to derive a large percentage of our

future revenue for M-Enoxaparin through contracts with GPOs. Currently, a relatively small number of GPOs control a substantial portion of generic pharmaceutical sales to hospital customers. In order to establish and maintain contracts with these GPOs, we believe that we, in collaboration with Sandoz, will 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 contracts may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours, limiting access of M-Enoxaparin to certain hospital segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by our customers, including the GPOs, wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our products. We anticipate that M356 will be primarily distributed through retail channels and mail order services. If we are unable to establish and maintain arrangements with all of these customers, future sales of our products, including M-Enoxaparin and M356, our revenues and our 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, 2007, we had cash, cash equivalents and marketable securities totaling $141.3 million. For the nine months ended September 30, 2007, we had a net loss of $54.6 million and used cash in operating activities of $47.2 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 timing of FDA approval of the products of our competitors;

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 that is not otherwise covered by our collaboration agreement, or potential patent litigation 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 for our business success. Our employment arrangements with our 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 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. 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.

***We may acquire or make investments in companies or technologies that could have an adverse effect on our business, results of operations and financial condition or cash flows.***

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

we may find that the acquired company or assets does 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;

difficulty integrating the operations and personnel of the acquired business, and difficulty retaining the key personnel of the acquired business;

difficulty incorporating the acquired technologies;

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;

disruption or diversion of management s attention by transition or integration issues and the complexity of managing diverse locations;

difficulty maintaining uniform standards, internal controls, procedures and policies;

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 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.

**Risks Relating to Development and Regulatory Approval**

***If we are not able to obtain regulatory approval for commercial sale of our generic product candidates as therapeutic equivalents to their corresponding reference listed drugs, including M-Enoxaparin, 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. 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 form, strength 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. In addition, we may be required to conduct *in vivo* studies to demonstrate that our generic versions of complex drugs are bioequivalent to the branded products upon which they are based, meaning typically that there are no significant differences 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 therapeutic equivalence of our generic versions of complex drugs to the reference listed 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 and their respective branded drugs are chemical equivalents. The FDA may require additional information, including, for example, animal or human testing, to determine therapeutic equivalence 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 receive FDA 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 interchangeability for generic versions of complex drug products, or requires us to conduct clinical trials or other lengthy processes, the commercialization of some of our development 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 follow-on versions of complex protein drugs, and if the U.S. Congress does not take action to create an abbreviated regulatory pathway for protein products, then the uncertainty about the value of our glycoprotein program will be increased.***

The regulatory climate for follow-on versions of protein products in the U.S. remains uncertain. Although there has been recent legislative activity, there is currently no established statutory or regulatory pathway for approval of follow-on versions of most protein drugs. The FDA has approved the majority of protein products under the Public Health Service Act, or PHSA, through the use of BLAs. Unlike drugs approved through the submission of NDAs, under section 505 of the Federal Food, Drug, and Cosmetic Act, or the FDCA, there is no provision in the PHSA for an abbreviated BLA approval pathway, 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 follow-on products. Moreover, even for proteins originally approved as NDAs, there is uncertainty as to what data the FDA may deem is necessary to demonstrate the

sameness required for approval of an ANDA under section 505(j) of the FDCA. In addition, there has been opposition to the FDA s use of section 505(b)(2), which allows an applicant to rely on information from published scientific literature and/or a prior approval of a similar drug, to approve follow-on versions of protein and other complex drug products approved under section 505 of the FDCA.

Although the FDA has previously stated its intention to draft guidance that is broadly applicable to follow-on protein products, the agency has not issued such guidance to date and may never do so. Protracted timelines and failure of the FDA to establish standards for approval of follow-on protein products or failure of the U.S. Congress to enact legislation establishing an abbreviated pathway for approval for follow-on products to approved BLA products could reduce the value of, or render obsolete, our glycoprotein program.

***If our preclinical studies and clinical trials for our development candidates, including M118, 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 are 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.

A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize M118 or our other drug candidates, including:

regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

our preclinical studies or clinical trials may produce negative or inconclusive results, and we may be required to conduct additional preclinical studies or clinical trials or we may abandon projects that we previously expected to be promising;

enrollment in our clinical trials may be slower than we anticipate, resulting in significant delays, and participants may drop out of our clinical trials at a higher rate than we anticipate;

we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;

regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

the cost of our clinical trials may be greater than we anticipate; and

the effects of our drug candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

The results from preclinical testing of a development candidate may not predict the results that will be obtained in human clinical trials. If we are required to conduct additional clinical trials or other testing of M118 or our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other tests, or if the results of these trials are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for our drug candidates or we may not be able to obtain marketing approval at all. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or potential products. If any of these events occur, our business will be materially harmed.

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

We intend in the future to market our products outside of 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 the numerous and varying regulatory requirements of each jurisdiction. The approval procedure and requirements varies among countries, and can require, among other things, submitting or conducting additional testing in each jurisdiction. 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 any other foreign country 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 of 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 drug products 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 new or 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. In addition, neither we, nor any of our third-party collaborators, are permitted to employ in any capacity, any individual who has been debarred under the FDA s Application Integrity Policy, and if such person is or has been so employed, the FDA may delay its review and approval of some or all of our applications, reject certain studies, withdraw approval of our applications, and take other adverse administrative action against us.

***If third-party payors do not adequately reimburse customers for any of our approved products, 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 product 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, Medicaid or other 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, changed 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, expanded Medicare coverage for drug purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered drugs, and provides authority for limiting the number of drugs that will be covered in any therapeutic class and provides 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 generally 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 separate 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; other proposed legislation would remove restrictions on CMS ability to negotiate discounts directly with prescription drug manufacturers provided through the Medicare program. 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 efforts by manufacturers of branded products to delay or limit the use of generics are successful, our sales of technology-enabled generic products may suffer.***

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

settling patent lawsuits with generic companies, resulting in such patents remaining an obstacle for generic approval by others;

innovator companies settling paragraph IV patent litigation with generic companies to prevent the expiration of the 180-day generic marketing exclusivity period or to delay the triggering of such exclusivity period;

submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted generic drug applications;

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

pursuing new patents for existing products or processes which could extend patent protection for a number of years or otherwise delay the launch of generic drugs; and

attaching special patent extension amendments to unrelated federal legislation.

In February 2003, Aventis filed a Citizen Petition with the FDA requesting that the FDA withhold approval of any ANDA for a generic version of Lovenox until and unless the FDA determines that the manufacturing process used by the generic applicant is equivalent to the process used to make Lovenox, or until the generic applicant demonstrates through clinical trials that its product is equally safe and effective as Lovenox, and unless the generic product is shown to contain a specific molecular structure. Teva, Amphastar, and others have filed comments opposing the Petition, and Aventis has filed numerous supplements and reply comments in support of its Petition. The FDA has yet to rule on the Petition, and if the FDA ultimately grants the Petition, we and Sandoz may be unable to obtain approval of our ANDA for M-Enoxaparin, which would materially harm our business.

Further, some manufacturers of branded products have engaged in state-by-state initiatives to enact legislation that restricts 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, 2006, 2005 and 2004, we spent approximately $31,000, $19,000, and $25,000, 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 and, for claims not covered by workers compensation insurance, employer s liability insurance, 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. 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 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 USPTO 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 we are infringing their intellectual property or 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, or pending the outcome of litigation, a court could issue a temporary injunction or a permanent injunction preventing us from marketing and selling the patented drug or other technology for the life of the patent that we have allegedly or 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 any activities, including 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, we could incur substantial costs, substantial liability for damages and may 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 patent or other proprietary rights in jurisdictions where we intend to market our products, including the United States, the European Union, and many other foreign jurisdictions. Alternatively, we may be subject to claims of patent infringement in jurisdictions where we intend to market our products. The cost to us of any litigation or other proceeding relating to determining the validity of intellectual property rights, even if resolved in our favor, could be substantial and 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 may have substantially greater resources. Moreover, the failure to obtain a favorable outcome in any litigation in a jurisdiction where there is a claim of patent infringement could significantly delay marketing of our products in that particular jurisdiction. The costs and 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 our obligations with regard to our exclusive in-licenses, they 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.

**Risks Relating to Our Dependence on Third Parties**

***Our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration are important to our business. If Sandoz fails to adequately perform under either collaboration, or we or Sandoz terminate all or a portion of either collaboration, the development and commercialization of some of our drug candidates, including injectable enoxaparin, would be delayed or terminated and our business would be adversely affected.***

Under our 2003 Sandoz Collaboration, we and Sandoz agree to exclusively work with each other in the development and commercialization of injectable enoxaparin within the United States. We also granted to Sandoz the right to negotiate additional rights for certain products under certain circumstances. Under our 2006 Sandoz Collaboration, we and Sandoz agree to exclusively work with each other in the development and commercialization of four follow-on and complex generic products for sale in specified regions of the world, including M356 and the expansion of M-Enoxaparin activity into the European Union.

*2003 Sandoz Collaboration*

Either we or Sandoz may terminate the 2003 Sandoz Collaboration for material uncured breaches or certain events of bankruptcy or insolvency by the other party. Sandoz may also terminate the 2003 Sandoz Collaboration if the injectable enoxaparin 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 the 2003 Sandoz Collaboration is terminated other than due to our uncured breach or bankruptcy, 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, which could cause significant delays that could prevent us from completing the development and commercialization of injectable enoxaparin. If Sandoz terminates the 2003 Sandoz Collaboration due to our uncured breach or bankruptcy, Sandoz would retain the exclusive right to develop and commercialize injectable enoxaparin in the United States. In that event, we would no longer have any influence over the development or commercialization strategy of injectable M-Enoxaparin in the United States. In addition, 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 and the European Union. Accordingly, if Sandoz terminates the 2003 Sandoz Collaboration, 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.

*2006 Sandoz Collaboration*

Either we or Sandoz may terminate the Definitive Agreement for material uncured breaches or certain events of bankruptcy or insolvency by the other party. In addition, the following termination rights apply to some of the products, on a product-by-product basis: (i) if clinical trials are required, (ii) at Sandoz convenience within a certain time period, (iii) if the parties agree, or the relevant regulatory authority states in writing, that our intellectual property does not contribute to product approval, (iv) if Sandoz decides to permanently cease development and commercialization of a product, or (v) by either party with respect to certain products if, following a change of control of the other party, the other party fails to perform its material obligations with respect to such product. For some of the products, for any termination of the Definitive Agreement other than a termination by Sandoz due to our uncured breach or bankruptcy, or a termination by us alone due to the need for clinical trials, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize the particular product. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. For some products, if Sandoz terminates the Definitive Agreement due to our uncured breach or bankruptcy, or if there is a termination by us alone due to the need for clinical trials, Sandoz would retain the exclusive right to develop and commercialize the applicable product. In that event, we would no longer have any influence over the development or commercialization strategy of such product. In addition, for other products, if Sandoz terminates due to our uncured breach or bankruptcy, Sandoz retains a right to license certain of our intellectual property without the obligation to make any additional payments for such licenses. For certain products, if the Definitive Agreement is terminated other than due to our uncured breach or bankruptcy, neither party will have a license to the other party s intellectual property. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. Accordingly, if the Definitive Agreement is terminated, our introduction of certain products may be significantly delayed, or our revenues may be significantly reduced either 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 and clinical 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 or elect to enter into alliances or collaborations with other companies to supplement and enhance our own capabilities or fund our development efforts. If we are unsuccessful in forming or maintaining these alliances on favorable terms, or if any collaborative partner terminates or fails to perform its obligations, 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.

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.

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 or delays in bringing our drug candidates to market will reduce their competitiveness and prevent us from generating sales revenues, which may substantially harm our business.

Furthermore, in an effort to continually update and enhance our proprietary technology platform we enter into agreements with other companies to develop, license, acquire and/or collaborate on various technologies. If we are unable to enter into the desired agreements, if the agreements do not yield the intended results or if the agreements terminate, we may need to find alternative approaches to such technology needs. If any of these occur, the development and commercialization of one or more drug candidates could be delayed, curtailed or terminated, any of which may adversely affect our business.

***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.

**General Company Related Risks**

***Our directors, executive officers and major stockholders have substantial influence or 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 39.8% of our outstanding common stock as of September 30, 2007. As a result, these stockholders, if acting together, may have the ability to determine the outcome of or influence 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 the M-Enoxaparin ANDA or other adverse FDA decisions relating to M-Enoxaparin, including the FDA requiring clinical trials as a condition to M-Enoxaparin approval;

FDA approval of other ANDAs for generic versions of Lovenox;

litigation involving our company or our general industry or both;

a decision in favor of Sanofi-Aventis in any of the current patent litigation matters, or a settlement related to any of those cases;

results or delays in our or our competitors clinical trials or regulatory filings;

failure to demonstrate therapeutic equivalence with respect to our technology-enabled generic product candidates;

failure to demonstrate 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 6. Exhibits.**

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| 10.1# | Restricted Stock Agreement between the Registrant and Richard P. Shea dated August 15, 2007. |
| 10.2 | Purchase Agreement between Alnylam Pharmaceuticals, Inc. and the Company dated October 31, 2007. |
| 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. |

# Management contract or compensatory plan or arrangement.

**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 8, 2007

By: /s/ Craig A. Wheeler
Craig A. Wheeler, President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2007

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