MOMENTA PHARMACEUTICALS INC

FORM 10-Q
(Quarterly Report)

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Telephone	617 491-9700
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Industry	Biotechnology & Drugs
Sector	Healthcare
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended June 30, 2008

☐ **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 ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐

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

Indicate the number of shares outstanding of each of the Registrant's classes of Common Stock as of July 31, 2008.

Class	**Number of Shares**
Common Stock $0.0001 par value	36,827,434

MOMENTA PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 38,043	$ 33,038
Marketable securities	71,332	102,899
Accounts receivable	—	747
Unbilled collaboration revenue	2,975	9,037
Prepaid expenses and other current assets	909	1,984
Total current assets	113,259	147,705
Property and equipment, net	15,488	15,296
Intangible assets, net	3,303	3,495
Restricted cash	1,778	1,778
Other assets	24	24
Total assets	$ 133,852	$ 168,298
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,485	$ 9,132
Accrued expenses	4,593	5,973
Deferred revenue	2,162	2,180
Line of credit obligations	267	721
Capital lease obligations	1,769	1,696
Lease financing liability	663	640
Deferred rent	70	70
Other current liabilities	2,000	2,000
Total current liabilities	14,009	22,412
Deferred revenue, net of current portion	9,146	10,212
Line of credit obligations, net of current portion	—	17
Capital lease obligations, net of current portion	5,370	6,273
Lease financing liability, net of current portion	1,344	1,681
Deferred rent, net of current portion	128	163
Total liabilities	29,997	40,758
Stockholders' equity:		
Preferred stock, $0.01 par value; 5,000 shares authorized at June 30, 2008 and December 31, 2007, 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, 36,785 and 36,489 shares issued and outstanding at June 30, 2008 and December 31, 2007, respectively	4	4
Additional paid-in capital	326,476	321,604
Accumulated other comprehensive income	84	332
Accumulated deficit	(222,709)	(194,400)
Total stockholders' equity	103,855	127,540
Total liabilities and stockholders' equity	$ 133,852	$ 168,298

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 June 30,		Six Months Ended June 30,	
	2008	2007	2008	2007
Collaboration revenue	$ 3,563	$ 4,175	$ 7,714	$ 6,417
Operating expenses:				
Research and development*	12,938	16,986	25,851	30,757
General and administrative*	6,326	8,006	12,107	15,710
Total operating expenses	19,264	24,992	37,958	46,467
Loss from operations	(15,701)	(20,817)	(30,244)	(40,050)
Other income (expense):				
Interest income	938	2,232	2,366	4,685
Interest expense	(207)	(174)	(431)	(357)
Net loss	$ (14,970)	$ (18,759)	$ (28,309)	$ (35,722)
Basic and diluted net loss per share	$ (0.42)	$ (0.53)	$ (0.79)	$ (1.00)
Shares used in computing basic and diluted net loss per share	35,773	35,613	35,756	35,599

*Includes the following stock-based compensation expense:

Research and development	$ 942	$ 1,262	$ 1,678	$ 2,508
General and administrative	$ 1,609	$ 2,176	$ 2,876	$ 4,445

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)

	Six Months Ended June 30,	
	2008	2007
Operating activities:		
Net loss	$ (28,309)	$ (35,722)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,871	1,547
Stock-based compensation expense	4,554	6,953
Accretion of discount on investments	(1,336)	(3,427)
Realized gain on sales of marketable securities	(47)	—
Purchase of in-process research and development	—	737
Amortization of intangible assets	192	74
Loss on disposal of assets	—	43
Changes in operating assets and liabilities:		
Accounts receivable	747	—
Unbilled collaboration revenue	6,062	683
Prepaid expenses and other current assets	1,075	(251)
Accounts payable	(6,647)	990
Accrued expenses	(1,380)	41
Deferred rent	(35)	121
Deferred revenue	(1,084)	(168)
Net cash used in operating activities	(24,337)	(28,379)
Investing activities:		
Purchase of intangible assets	—	(2,500)
Purchases of property and equipment	(2,063)	(4,575)
Purchases of marketable securities	(60,189)	(146,950)
Maturities of marketable securities	84,550	174,420
Sales of marketable securities	8,341	—
Net cash provided by investing activities	30,639	20,395
Financing activities:		
Proceeds from issuance of common stock under stock plans	318	453
Payments on financed leasehold improvements	(314)	(293)
Proceeds from capital lease obligations	—	2,318
Principal payments on capital lease obligations	(830)	(450)
Principal payments on line of credit	(471)	(432)
Net cash (used in) provided by financing activities	(1,297)	1,596
Net increase (decrease) in cash and cash equivalents	5,005	(6,388)
Cash and cash equivalents, beginning of period	33,038	22,351
Cash and cash equivalents, end of period	$ 38,043	$ 15,963
Supplemental cash flow information:		
Cash paid for interest	$ 431	$ 357
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. The Company presently derives all of its revenue from research collaborations with pharmaceutical companies.

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 six months ended June 30, 2008 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, 2007, which was filed with the Securities and Exchange Commission ("SEC") on March 10, 2008.

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. During the six months ended June 30, 2008, the Company recorded realized gains on marketable securities of $47,000. There were no realized gains or losses on marketable securities during the three months ended June 30, 2008 and during the three and six months ended 2007. 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 during the six months ended June 30, 2008.

Revenue Recognition

The Company recognizes revenue from research and development collaboration agreements in accordance with SEC 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") Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* .

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. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized in accordance with EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* . The capitalized amounts are expensed as the related goods are delivered or the services are received.

Stock-Based Compensation

The Company's 2004 Stock Incentive Plan, as amended (the "Incentive Plan"), allows for the granting of incentive and nonstatutory stock options, restricted stock awards, stock appreciation rights and other stock-based awards to employees, officers, directors, consultants and advisors. At December 31, 2007, the Company was authorized to issue up to 5,750,838 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, 2008, the Company's Board of Directors increased the number of authorized shares of common stock available for issuance under the Incentive Plan by 1,823,491 shares.

As discussed more fully in Note 5, the Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment* , or SFAS 123R, effective January 1, 2006 under the modified prospective transition method of adoption. Under this method, the provisions of SFAS 123R apply to all awards granted or modified after the date of adoption. In addition, the unrecognized expense of awards not yet vested at the date of adoption, determined under the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* , or SFAS 123, is being recognized in the Company's statements of operations in the periods after the date of adoption over the remaining vesting periods, if any. Stock-based compensation expense primarily relates to stock options, restricted stock and stock issued under the Company's stock option plans and employee stock purchase plan. The Company recognizes stock-based compensation expense equal to the fair value of stock options on a straight-line basis over the requisite service period. Restricted stock awards are recorded as compensation cost, based on the market value on the date of the grant, on a straight-line basis over the requisite service period.

In accordance with SFAS 123R, the fair value of each option award was estimated on the date of grant using the Black-Scholes-Merton option-pricing model. The Company considers, among other factors, the implied volatilities of its own currently traded options to provide an estimate of volatility based upon current trading activity. The Company concluded that a blended volatility rate based upon the most recent three-and-one-half year period of its own historical performance, as well as the implied volatilities of its own currently traded options, appropriately reflects the expected volatility of its stock going forward. The Company uses a blend of its own historical data and peer data to estimate option exercise and employee termination

behavior, adjusted for known trends, to arrive at the estimated expected life of an option. For purposes of identifying peer entities, the Company considers characteristics such as industry, stage of life cycle and financial leverage. The Company updates these assumptions on a quarterly basis to reflect recent historical data. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

SFAS 123R requires the application of an estimated forfeiture rate to current period expense to recognize stock-based compensation expense only for those awards expected to vest. The Company estimates forfeitures based upon historical data, adjusted for known trends, and will adjust its estimate of forfeitures if actual forfeitures differ, or are expected to differ from such estimates. Subsequent changes in estimated forfeitures will be recognized through a cumulative adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods.

Unvested stock options held by consultants have been 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* . Stock-based compensation expense 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* , or FIN 28.

Income Taxes

The Company accounts for income taxes under SFAS No. 109, *Accounting for Income Taxes* , or SFAS 109. 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 FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109* , or FIN 48, on January 1, 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition.

As a result of adopting FIN 48, as of January 1, 2007, the Company recorded a reduction in its deferred tax asset valuation allowance of approximately $3.1 million for unrecognized tax benefits related to research and development tax credit and net operating losses. During the six months ended June 30, 2008, the Company had no material unrecognized tax benefits and no adjustments to its deferred tax assets under FIN 48. The Company's practice has been and continues to be to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which was zero at both the adoption date and for the six months ended June 30, 2008.

The Company files income tax returns in the United States federal jurisdiction and multiple state jurisdictions. The Company is no longer subject to any tax assessment from an income tax examination for years before 2004, except to the extent that in the future it utilizes net operating losses or tax credit carryforwards that originated before 2004. 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 June 30, 2008 and 2007 consists entirely of unrealized gains and losses on available-for-sale securities. Comprehensive loss for the three months ended June 30, 2008 and 2007 was $15.2 million and $18.7 million, respectively. Comprehensive loss for the six months ended June 30, 2008 and 2007 was $28.6 million and $35.7 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 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 June 30, 2008 have come from one collaborative partner.

3. Intangible assets

As of June 30, 2008 and December 31, 2007, intangible assets, net of accumulated amortization, are as follows (in thousands):

		June 30, 2008		December 31, 2007	
	Estimated Life	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Core technology	12 years	$ 3,593	$ (358)	$ 3,593	$ (209)
Non-compete agreement	2 years	170	(102)	170	(59)
Total intangible assets		$ 3,763	$ (460)	$ 3,763	$ (268)

Amortization is computed using the straight-line method over the useful lives of the respective intangible assets. Amortization expense was $0.1 million for each of the three months ended June 30, 2008 and 2007. Amortization expense was $0.2 million and $0.1 million during the six months ended June 30, 2008 and 2007, respectively.

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

4. 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 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 $0.6 million 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 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 $0.6 million non-refundable up-front payment as revenue on a straight line basis over the estimated M-Enoxaparin development period. In June 2008, the Company revised its estimate of the development period from 5 years to approximately 5.5 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 six months ended June 30, 2008. The Company recognized revenue relating to this up-front payment of approximately $6,000 and $12,000 for the three and six months ended June 30, 2008, 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 Issue 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 six months ended June 30, 2008 or during 2007.

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 Global Market 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. The Company recognized revenue relating to this paid premium of approximately $0.5 million and $1.1 million for the three and six months ended June 30, 2008, respectively. 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 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 AG. 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, is 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.

5. Stock-Based Compensation

Total compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the Company's employee stock purchase plan, for the three months ended June 30, 2008 and 2007 was $2.6 million and $3.4 million, respectively. Total compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the Company's employee stock purchase plan, for the six months ended June 30, 2008 and 2007 was $4.6 million and $7.0 million, respectively.

The Company recorded stock-based compensation expense of $1.8 million related to outstanding employee stock option grants and the Company's employee stock purchase plan during each of the three months ended June 30, 2008 and 2007. The Company recorded stock-based compensation expense of $3.1 million and $3.4 million related to outstanding employee stock option grants and the Company's employee stock purchase plan during the six months ended June 30, 2008 and 2007, respectively. During the six months ended June 30, 2008, the Company granted options to purchase an aggregate of 942,081 shares of the Company's common stock. The Company recorded stock-based compensation expense, using the accelerated method under FIN 28, of $0 and $4,000 related to outstanding consultant stock option grants during the six months ended June 30, 2008 and 2007, respectively. No stock-based compensation expense was recorded related to outstanding consultant stock option grants during the three months ended June 30, 2008 and 2007. The weighted average grant date fair value of options granted to employees was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended June 30, 2008 and 2007 was $9.20 and $8.23 per option, respectively. The weighted average grant date fair value of option awards granted during the six months ended June 30, 2008 and 2007 was $6.22 and $8.44 per option, respectively. The following tables summarize the weighted average assumptions the Company used in its fair value calculations at the date of grant:

	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	Three Months Ended June 30, 2008	Three Months Ended June 30, 2007	Three Months Ended June 30, 2008	Three Months Ended June 30, 2007
Expected volatility	83%	76%	83%	72%
Expected dividends	—	—	—	—
Expected life (years)	5	6	0.5	0.5
Risk-free interest rate	3.6%	4.9%	2.1%	5.2%

	Stock Options		Employee Stock Purchase Plan	
	Six Months Ended June 30, 2008	Six Months Ended June 30, 2007	Six Months Ended June 30, 2008	Six Months Ended June 30, 2007
Expected volatility	83%	75%	79%	70%
Expected dividends	—	—	—	—
Expected life (years)	6	6	0.5	0.5
Risk-free interest rate	3.3%	4.8%	3.3%	5.2%

At June 30, 2008, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $14.0 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.6 years.

The Company has also made awards of restricted common stock to certain employees, officers and directors. During the six months ended June 30, 2008, the Company awarded 226,760 shares of restricted common stock to certain employees and officers. Awards generally fully vest four years from the grant date, although certain awards have performance conditions such as the commercial launch of M-Enoxaparin in the U.S.

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of June 30, 2008 are summarized below:

Vesting Schedule	Nonvested Shares (in thousands)
Time-based	577
Performance-based	430
Nonvested at June 30, 2008	1,007

In June 2008, 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 $27,000 less than had the estimate remained unchanged for the six months ended June 30, 2008. The Company recorded stock-based compensation expense of $0.8 million and $1.6 million related to outstanding restricted stock awards during the three months ended June 30, 2008 and 2007, respectively. The Company recorded stock-based compensation expense of $1.5 million and $3.6 million related to outstanding restricted stock awards during the six months ended June 30, 2008 and 2007, respectively. As of June 30, 2008, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $5.4 million, including estimated forfeitures, which is expected to be recognized over the weighted average remaining requisite service period of approximately 2 years.

During the six months ended June 30, 2008, holders of options issued under the Company's stock plans exercised their right to acquire an aggregate of 49,791 shares of common stock. Additionally, the Company issued 26,192 shares of common stock to employees under the Company's employee stock purchase plan during the six months ended June 30, 2008.

6. Fair Value Measurements

The Company adopted SFAS No. 157, *Fair Value Measurements* , or SFAS 157, as of January 1, 2008 and the adoption did not have a material impact on the consolidated financial position, results of operations or cash flows of the Company. In accordance with the provisions of FSP No. FAS 157-2, *Effective Date of FASB Statement No. 157,* the Company elected to defer implementation of SFAS 157 as it relates to non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. The Company is evaluating the impact, if any, SFAS 157 will have on its non-financial assets and liabilities.

SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with U.S. GAAP and enhances disclosure requirements for fair value measurements. SFAS 157 establishes a three-level valuation hierarchy for disclosure of fair value measurements. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the measurement of fair value. The three levels are defined as follows:

- Level 1 – inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 – inputs to the valuation methodology are other observable inputs, including quoted prices for similar assets and liabilities in active or non-active markets, inputs other than quoted prices that are observable for the asset or liability, and inputs that are not directly observable, but are corroborated by the observable market data.
- Level 3 – inputs to the valuation methodology are unobservable for the asset or liability.

A Level 1 classification is applied to any asset that has a readily available quoted price from an active market where there is significant transparency in the executed / quoted price. A Level 2 classification is applied to assets whose fair values are determined using quoted prices in active markets for similar assets or inputs other than quoted prices that are observable for the asset.

Assets measured at fair value on a recurring basis at June 30, 2008 are as follows:

Description	June 30, 2008	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 37,972	$ 37,972	$ —	$ —
Marketable securities	71,332	—	71,332	—
Total	$ 109,304	$ 37,972	$ 71,332	$ —

The Company also adopted the provisions of SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities – Including an Amendment of FASB Statement No. 115*, or SFAS 159, in the first quarter of 2008. SFAS 159 allows the Company to choose to measure eligible assets and liabilities at fair value with changes in value recognized in earnings. Fair value treatment may be elected either upon initial recognition of an eligible asset or liability or, for an existing asset or liability, if an event triggers a new basis of accounting. The Company did not elect to re-measure any of its existing financial assets or liabilities under the provisions of SFAS 159.

7. Recently Issued Accounting Standards

In December 2007, EITF Issue No. 07-01, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, or EITF 07-01, was issued. EITF 07-01 prescribes the accounting for collaborations. It requires certain transactions between collaborators to be recorded in the income statement on either a gross or net basis when certain characteristics exist in the collaboration relationship. EITF 07-01 is effective for all of the Company's collaborations existing after January 1, 2009. The Company is evaluating the impact, if any, EITF 07-01 will have on the consolidated financial statements.

In December 2007, SFAS No. 141(R), *Business Combinations* , or SFAS 141(R), was issued. This Standard will require the Company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date when the Company acquires another business. In addition, the Company will capitalize IPR&D when it acquires another business and either amortize it over the life of the product or write it off if the project is abandoned or impaired. SFAS 141(R) is effective for transactions occurring on or after January 1, 2009.

In December 2007, SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51* , or SFAS 160, was issued. SFAS 160 changes the accounting for and reporting of noncontrolling interests (formerly known as minority interests) in consolidated financial statements. SFAS 160 is effective January 1, 2009. When implemented, prior periods will be recast for the changes required by SFAS 160. The adoption of this pronouncement is not expected to have any impact on the Company's financial condition, results of operations or cash flows.

On March 19, 2008, SFAS No. 161, *Disclosures About Derivative Instruments and Hedging Activities* , or SFAS 161, was issued. SFAS 161 enhances the disclosure requirements for derivative instruments and hedging activities. SFAS 161 is effective January 1, 2009. Since SFAS 161 requires only additional disclosures concerning derivatives and hedging activities, adoption of SFAS 161 will not affect the Company's financial condition, results of operations or cash flows.

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 with a product pipeline of both novel and complex generic drugs. This pipeline is derived from our proprietary, innovative technology platform for the detailed structural analysis of complex mixture drugs. We use this platform to study the *structure* (thorough characterization of chemical components), *structure-process* (design and control of manufacturing process), and *structure-activity* (relating structure to biological and clinical activity) of complex mixture drugs, resulting in our product pipeline of both complex generic and novel drugs.

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, the 2003 Sandoz 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 under the 2003 Sandoz Collaboration to Sandoz AG. We refer to Sandoz AG and Sandoz Inc. collectively as Sandoz. In August 2005, Sandoz submitted an Abbreviated New Drug Application, or ANDA, to the U.S. Food and Drug Administration, or FDA, for the syringe formulation of M-Enoxaparin. The ANDA was amended in 2006 to include a paragraph IV certification stating that Sanofi-Aventis' patents for Lovenox listed in the FDA's listing of approved drug products, the Orange Book, are, among other things, invalid or unenforceable.

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. In June 2007, we and Sandoz AG executed a definitive collaboration and license agreement, or the Definitive Agreement, which superseded the MOU. We and Sandoz amended the Definitive Agreement in April 2008. 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.

Since our inception in May 2001, we have incurred annual net losses. As of June 30, 2008, we had an accumulated deficit of $222.7 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 at a per share price of $15.93 (the closing price of our common stock on the NASDAQ Global Market was $13.05 on the date of purchase) for an aggregate purchase price of $75.0 million, resulting in an equity premium of $13.6 million. To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates.

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, $67.6 million of revenue from our inception through June 30, 2008. 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. In November 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin was not approvable in its then-current form because the ANDA did not adequately address the potential for immunogenicity of the drug product. In early 2008, we and Sandoz provided the FDA with a proposed plan for addressing the potential for the immunogenicity of the drug product. In April 2008, the FDA responded to the proposal and provided additional guidance which indicated general concurrence with our approach and proposal. The FDA also requested additional data from in vitro and in vivo animal tests, the testing of additional samples for tests previously proposed, and additional information regarding certain of the methods proposed. The FDA has not requested human clinical trials at this time; however, there can be no assurances that the FDA will not require such studies in the future. We and Sandoz anticipate that we will be able to submit an amendment to the M-Enoxaparin ANDA containing the requested additional data during the third quarter of 2008.

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 anticoagulant 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 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile. In October 2007, we

began a Phase 2a 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 March 2007, we filed our IND for our M118 subcutaneous formulation, and in May 2007 began Phase 1 clinical trials to evaluate its human safety, tolerability and pharmacokinetic profile.

M356

M356 is designed 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 Relapsing-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 AG have agreed to jointly develop, manufacture and commercialize glatiramer acetate injection, the generic name for Copaxone, which we refer to as M356. We are responsible for funding substantially all of the U.S.-related M356 development costs, with Sandoz AG responsible for legal and commercialization costs. Outside of the U.S., we and Sandoz AG share equally the development costs, with Sandoz responsible for commercialization and legal costs. In accordance with the 2006 Sandoz Collaboration, in December 2007, Sandoz submitted to the FDA an ANDA in its name containing a Paragraph IV certification seeking approval to market M356 in the United States. On July 9, 2008, the FDA notified Sandoz that it had accepted the ANDA for review as of December 27, 2007. In addition, the FDA's published database indicates that the first substantially complete ANDA submitted for glatiramer acetate injection containing a Paragraph IV certification was filed on December 27, 2007.

Glycoproteins

Glycoproteins are proteins to which sugar molecules are attached. Examples of glycoprotein drugs are erythropoietin, blood clotting factors and interferon beta. We are applying our technology to the development of generic or biosimilar glycoprotein drugs. We believe that this technology can further be used in assisting pharmaceutical and biotechnology companies in developing improved and next-generation versions of their branded products by analyzing and modifying the sugar structures contained in the branded products, and can also be used to engineer novel complex mixture drugs.

Our glycoprotein program is focused on extending our technology for the analysis of complex sugars to glycoproteins. The goal of the program is to facilitate the development of generic or biosimilar versions of major marketed glycoprotein drugs.

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.

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 June 30, 2008 and 2007

Revenue

Revenues for the three months ended June 30, 2008 and 2007 were $3.6 million and $4.2 million, respectively. Revenues for the three months ended June 30, 2008 and 2007 consist of (i) amounts earned by us under our 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs 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 month period ended June 30, 2008 compared to the three months ended June 30, 2007 decreased $0.6 million due primarily to a decrease of $0.8 million in reimbursable development expenditures on our M356 and glycoprotein programs associated with the 2006 Sandoz Collaboration and a $0.2 million decrease in reimbursable development expenditures associated with preparing for the potential commercial launch of M-Enoxaparin in the U.S. These decreases were offset by a $0.4 million increase related to the amortization of the equity premium.

Research and Development

The following table summarizes the primary components of our research and development expenditures for our principal research and development programs for the three months ended June 30, 2008 and 2007.

Research and Development Program	Three Months Ended June 30, 2008	Three Months Ended June 30, 2007
	(in thousands)	
Development programs	$ 11,490	$ 15,939
Discovery programs	1,442	986
Other research	6	61
Total research and development expense	$ 12,938	$ 16,986

Research and development expense for the three months ended June 30, 2008 was $12.9 million compared to $17.0 million for the three months ended June 30, 2007. The decrease of $4.0 million from 2007 to 2008 primarily resulted from a decrease of $3.9 million in manufacturing and process development costs and research conducted by third parties in support of our M356 and M-Enoxaparin programs, a decrease of $0.7 million in in-process research and development due to a charge taken in April 2007 related to the Parivid asset purchase, a decrease of $0.3 million in stock-based compensation expense primarily due to a revision of the expected vesting date on certain performance-based restricted stock awards and a decrease of $0.1 million in personnel and related costs. These decreases were offset by an increase of $1.0 million in clinical trial costs for our M118 program.

The lengthy process of securing FDA approvals for new drugs requires the expenditure of substantial resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals would materially adversely affect our product development efforts and our business overall. Accordingly, we cannot currently estimate, with any degree of certainty, the amount of time or money that we will be required to expend in the future on our product candidates prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate when, if ever, our product candidates will generate revenues and cash flows. We expect future research and development expenses to increase in support of our product candidates although expenses may fluctuate from quarter to quarter.

The decrease in expenditures on development programs of $4.4 million from 2007 to 2008 was primarily related to a decrease in our M356 and M-Enoxaparin program costs due to the timing of manufacturing and process development activity. This decrease was offset by an increase in headcount resources dedicated to our M118 program as we progress through the Phase 2a clinical trial.

The discovery program expenditures from 2007 to 2008 include an increase of approximately $0.5 million due to an increase in our oncology program expenditures representing additional resources dedicated to applying our analytical capabilities to drug discovery.

The decrease in other research expense 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 June 30, 2008 was $6.3 million, compared to $8.0 million for the three months ended June 30, 2007. General and administrative expense decreased by $1.7 million from 2007 to 2008 due to a decrease of $0.8 million in professional fees due to a reduction in legal activities, a decrease of $0.6 million in stock-based compensation expense resulting primarily from a revision of the expected vesting date on certain performance-based restricted stock awards, and $0.3 million in personnel and related costs due to lower placement fees.

We anticipate increases in general and administrative expenses to support our research and development programs including increases associated with the hiring of additional personnel. We expect to incur increased internal and external legal and business development costs to support our various product development efforts, which can vary from period to period.

Interest Income and Expense

Interest income was $0.9 million and $2.2 million for the three months ended June 30, 2008 and 2007, respectively. The decrease of $1.3 million from 2007 to 2008 was primarily due to lower average investment balances and lower interest rates.

Interest expense was $0.2 million for both the three months ended June 30, 2008 and 2007. We did not draw any additional amounts from our equipment line of credit during the three months ended June 30, 2008.

Six Months Ended June 30, 2008 and 2007

Revenue

Revenues for the six months ended June 30, 2008 and 2007 were $7.7 million and $6.4 million, respectively. Revenues increased $1.3 million due primarily to a $1.0 million increase related to the amortization of the equity premium and a $0.6 million increase of reimbursable development expenditures associated with preparing for the potential commercial launch of M-Enoxaparin in the U.S., offset by a decrease of $0.3 million in reimbursable development expenditures on our M356 and glycoprotein programs associated with 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 six months ended June 30, 2008 and 2007:

Research and Development Program	Six Months Ended June 30, 2008	Six Months Ended June 30, 2007
	(in thousands)	
Development programs	$ 22,856	$ 28,586
Discovery programs	2,989	2,018
Other research	6	153
Total research and development expense	$ 25,851	$ 30,757

Research and development expense for the six months ended June 30, 2008 was $25.9 million compared to $30.8 million for the six months ended June 30, 2007. The decrease of $4.9 million from 2007 to 2008 primarily resulted from a decrease of $5.9 million in manufacturing and process development costs and research conducted by third parties in support of our M356 and M-Enoxaparin programs, a decrease of $0.8 million in stock-based compensation expense primarily due to a revision of the expected vesting date on certain performance-based restricted stock awards and a decrease of $0.7 million in in-process research and development due to a charge taken in April 2007 related the Parivid asset purchase. These decreases were offset by an increase of $1.6 million in clinical trial costs for our M118 program and $0.9 million in personnel and related costs associated with the growth in our research and development organization.

The decrease in expenditures on development programs of $5.7 million from 2007 to 2008 was primarily related to a decrease in our M356 program and M-Enoxaparin costs due to the timing of manufacturing and process development activity. This decrease was offset by an

increase in headcount resources dedicated to our glycoprotein programs associated with 2006 Sandoz Collaboration and our M118 program as we progress through the Phase 2a clinical trial.

The discovery program expenditures from 2007 to 2008 include an increase of approximately $1.0 million due to an increase in our oncology program expenditures representing additional resources dedicated to applying our analytical capabilities to drug discovery.

The decrease in other research expense 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 six months ended June 30, 2008 was $12.1 million compared to $15.7 million for the six months ended June 30, 2007. General and administrative expense decreased by $3.6 million from 2007 to 2008 due to a decrease of $1.7 million in professional fees due to a reduction in legal activities, $1.6 million in stock-based compensation expense primarily due to a revision of the expected vesting date on certain performance-based restricted stock awards, and $0.3 million in personnel and related costs due to lower placement fees.

Interest Income and Expense

Interest income was $2.4 million and $4.7 million for the six months ended June 30, 2008 and 2007, respectively. The decrease of $2.3 million from 2007 to 2008 was primarily due to lower average investment balances and lower interest rates.

Interest expense was $0.4 million for both the six months ended June 30, 2008 and 2007. We did not draw any additional amounts from our equipment line of credit during the six months ended June 30, 2008.

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 2006 Sandoz Collaboration, and borrowings from our lines of credit and capital lease obligations. We expect to finance our current and planned operating requirements principally through our current cash, cash equivalents and marketable securities. We believe that these funds will be sufficient to meet our operating requirements through at least 2009. 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. We may, from time to time, seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources.

At June 30, 2008, we had $109.4 million in cash, cash equivalents and marketable securities. In addition, we held $1.8 million in restricted cash which serves as collateral for a letter of credit related to our facility lease. During the six months ended June 30, 2008 and 2007, our operating activities used $24.3 million and $28.4 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. For the six months ended June 30, 2008, our net loss adjusted for non-cash items was $23.1 million. In addition, the net change in our operating assets and liabilities used $1.3 million and resulted from: a decrease in accounts receivable of $0.7 million, due to the timing of cash receipts from our sole customer; a decrease in unbilled collaboration revenue of $6.1 million, resulting from decreased manufacturing and research costs for our M- Enoxaparin program; a decrease in accounts payable of $6.6 million, due to the payment of manufacturing and research costs for our M-Enoxaparin program and clinical trial costs for our M118 program; a decrease in accrued expenses of $1.4 million, resulting from the payment of annual bonuses earned during 2007; and decreased manufacturing and research costs for our M-Enoxaparin program. For the six months ended June 30, 2007, our net loss adjusted for non-cash items was $29.8 million. In addition, the net change in our operating assets and liabilities provided $1.4 million, primarily due to an increase in accounts payable of $1.0 million due to general increases in our business activities as a result of greater headcount and increased product development costs and a decrease in unbilled collaboration revenue of $0.7 million due to a decrease in reimbursable development activities for the M-Enoxaparin program. These changes were offset by an increase in prepaid expenses and other current assets of $0.3 million due to an increase in clinical trial activities for our M118 program.

Net cash provided by investing activities for the six months ended June 30, 2008 and 2007 was $30.6 million and $20.4 million, respectively. In the first six months of 2008, we used $60.2 million of cash to purchase marketable securities, and we received $92.9 million from sales and maturities of marketable securities. In the first six months of 2007, we used $147.0 million of cash to purchase marketable securities and received $174.4 million from maturities of marketable securities. In the first six months of 2008 and 2007, we used $2.1 million and $4.6 million, respectively, to purchase laboratory equipment and leasehold improvements. In the first six months of 2007, we paid $2.5 million in connection with entering into the asset purchase agreement with Parivid, LLC.

Net cash used in financing activities for the six months ended June 30, 2008 was $1.3 million. We received proceeds of $0.3 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of $1.3 million on our line of credit and lease agreement obligations and $0.3 million on financed leasehold improvements related to our corporate facility. Net cash provided by financing activities for the six months ended June 30, 2007 was $1.6 million. We had borrowings of $2.3 million on our lease agreement obligations and received proceeds of $0.5 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of $0.9 million on our line of credit and lease agreement obligations and $0.3 million on financed leasehold improvements related to our corporate facility.

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. The disclosures relating to our contractual obligations in our Annual Report on Form 10-K for the year ended December 31, 2007 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. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue

We record revenue on an accrual basis as it is earned and when amounts are considered collectible. Revenues received in advance of performance obligations or in cases where we have a continuing obligation to perform services are deferred and recognized over the performance period. 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 five and a half years and six years, respectively, from the applicable collaboration inception date. In June 2008, we revised our 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 our net loss or net loss per share for the three and six months ended June 30, 2008.

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.

Nonrefundable Advance Payments for Goods or Services

In July 2007, FASB ratified 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. The task force reached a consensus 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. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments should be charged to expense. Our adoption of EITF 07-3 on January 1, 2008 did not have a material impact on our results of operations, financial position or cash flows.

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 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.

We determine the fair value of each option award on the date of grant using the Black-Scholes-Merton option pricing model. Option valuation models require the input of highly subjective assumptions, including stock price volatility and expected term of an option. In determining our volatility, we have considered implied volatilities of currently traded options to provide an estimate of volatility based upon current trading activity in addition to our historical volatility. After considering other such factors as our stage of development and the length of time we have been public, we believe a blended volatility rate based upon historical performance, as well as the implied volatilities of currently traded options, best reflects the expected volatility of our stock going forward. Changes in market price directly affect volatility and could cause stock-based compensation expense to vary significantly in future reporting periods.

The expected term of awards represents the period of time that the awards are expected to be outstanding. We use a blend of our own historical employee exercise and post-vest termination behavior and expected term data from our peer group to arrive at the estimated expected life of an option. For purposes of identifying similar entities, we considered characteristics such as industry, stage of life cycle and financial leverage. We update these assumptions on a quarterly basis to reflect recent historical data. Additionally, we are required to estimate forfeiture rates to approximate the number of shares that will vest in a period to which the fair value is applied. We will continually monitor employee exercise behavior and may further adjust the estimated term and forfeiture rates in future periods. Increasing the estimated life would result in an increase in the fair value to be recognized over the requisite service period, generally the vesting period. Estimated forfeitures will be adjusted to actual forfeitures upon the vest date of the cancelled options as a cumulative adjustment on a quarterly basis. The risk-free interest rates used in the Black-Scholes-Merton option pricing model are based on the United States Treasury yield curve in effect for periods corresponding with the expected term of the stock option.

The value of our restricted stock awards is recognized as compensation cost in our consolidated statements 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 2008, we 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, our net loss for the six months ended June 30, 2008 was $27,000 less than had the estimate remained unchanged. The impact of this change in estimate on our net loss per share was not material.

During the three and six months ended June 30, 2008, we recognized total stock-based compensation expense under SFAS 123R of $2.6 million and $4.6 million, respectively. As of June 30, 2008, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $14.0 million, including estimated forfeitures, which will be amortized over the weighted-average remaining requisite service periods of 2.6 years. As of June 30, 2008, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $5.4 million, including estimated forfeitures, which will be amortized over the weighted-average remaining requisite service periods of approximately 2 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 June 30, 2008, 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 June 30, 2008. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15 (e) under the Securities Exchange Act of 1934, as amended, 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 Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’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 Securities Exchange Act of 1934, as amended, 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 June 30, 2008, 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 Securities Exchange Act of 1934, as amended) occurred during the fiscal quarter ended June 30, 2008 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 Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, 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.

Risks Relating to our Business

We have a limited operating history and have incurred a cumulative loss since inception. If we do not generate significant revenues, we will not be profitable.

We have incurred significant losses since our inception in May 2001. At June 30, 2008, our accumulated deficit was approximately $222.7 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 through either existing or new regulatory approval pathways; 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, depend on the successful development and commercialization of M-Enoxaparin.

In accordance with our 2003 Sandoz Collaboration, Sandoz has submitted ANDAs to the FDA 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 a New Drug Application, or NDA. In November 2007, Sandoz received a letter from the FDA stating that the syringe ANDA for M-Enoxaparin was not approvable, because the ANDA did not adequately address the potential for immunogenicity of the drug product. If we fail to answer the FDA's questions related to the potential for immunogenicity of the drug product to the satisfaction of the FDA, 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, or if we otherwise fail to meet FDA requirements for the ANDA (including, but not limited to, manufacturing and bioequivalence requirements) or fail to obtain FDA approval for, and successfully commercialize, M-Enoxaparin, we may

never realize revenue from this product and we may have to curtail our other product development programs. As a result, our business would be materially harmed.

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 "Approved Drug Products with Therapeutic Equivalence Evaluations," or 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, United States Patent No. 5,389,618, or the '618 Patent, and its counterpart, Reissue Patent No. 38,743, or the '743 Reissue Patent. Sanofi-Aventis has reported that the claims of the '618 Patent are identical or substantially identical to the corresponding claims of the '743 Reissue Patent. According to Sanofi-Aventis, by operation of law, the '618 Patent ceased to exist and has been replaced by the '743 Reissue Patent. According to the Orange Book, the '743 Reissue Patent expires February 14, 2012.

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

Amphastar/Teva Patent Infringement Lawsuit

In September 2003, prior to issuance of the '743 Reissue Patent, Sanofi-Aventis announced that it had received individual notices from Amphastar and Teva indicating that each had submitted to the FDA its own ANDA for enoxaparin with a paragraph IV certification. 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, after issuance of the '743 Reissue Patent, Amphastar and Teva each subsequently amended its own ANDA to include a second paragraph IV certification for the '743 Reissue Patent.

In June 2005, the District Court granted summary judgment in the Amphastar/Teva case, finding that both the '618 Patent and the '743 Reissue Patent were unenforceable due to Sanofi-Aventis' inequitable conduct before the United States Patent and Trademark Office, or USPTO. Thereafter, Sanofi-Aventis appealed the decision to the United States Court of Appeals for the Federal Circuit, or the Court of Appeals. In April 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 and, in February 2007, the District Court ruled in favor of Amphastar and Teva holding both the '618 Patent and the '743 Reissue Patent unenforceable by virtue of Sanofi-Aventis' inequitable conduct before the USPTO. Sanofi-Aventis appealed this ruling and, in May 2008, the Court of Appeals affirmed the District Court's ruling. In June 2008, Sanofi-Aventis petitioned the Court of Appeals for a rehearing *en banc* and that petition is under review by the Court of Appeals . Several parties have also filed friend of the court briefs in support of the petition for rehearing. The outcome of this litigation is highly uncertain and, depending on the decision of the Court of Appeals, may result in further procedural actions by the parties involved that might prolong any final determination of the litigation. Our ability to receive approval for M-Enoxaparin and launch M-Enoxaparin, and the timing of any such approval and launch, will depend in part upon the final outcome of this litigation. We cannot be certain what the outcome of the litigation will be or when it will be final.

Sandoz Patent Infringement Lawsuit

In August 2005, Sandoz submitted an ANDA to the FDA to obtain approval for the commercial manufacture, use and sale of the syringe formulation of enoxaparin and in 2006 Sandoz amended its ANDA by filing a paragraph IV certification stating, among other things, that the '618 Patent and '743 Reissue Patent are invalid and unenforceable. In response, Sanofi-Aventis brought a patent infringement suit against Sandoz in August 2006. Sandoz has moved for summary judgment finding unenforceability of the '618 Patent and '743 Reissue Patent based upon the decision in the Amphastar/Teva case, and the District Court has stayed the case against Sandoz until September 8, 2008.

In December 2006, Sandoz submitted 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 '743 Reissue 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 decision in the Amphastar/Teva case, and the District Court has stayed the case against Sandoz until September 8, 2008.

Continuing litigation could delay or prevent the introduction of M-Enoxaparin. Moreover, 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 '618 Patent and '743 Reissue Patent. Pharmaceutical companies frequently sue generic challengers over potential infringement of patents that are not listed in the Orange Book. Presently, we are not aware of any enoxaparin 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 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, the decision as to when to begin marketing M-Enoxaparin if the ANDA is approved will be determined jointly by us and Sandoz in most circumstances. However, Sandoz does have sole discretion over the decision as to when to begin marketing M-Enoxaparin under certain circumstances. Sandoz could decide to market M-Enoxaparin "at risk," that is 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, as a result of protracted litigation, 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 if Sanofi-Aventis decides to market its drug as a generic or license it to another company to be sold as a generic, both known as authorized generics, the financial returns to us from the marketing of M- Enoxaparin 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, our commercial launch may be delayed 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 Sandoz 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 its 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 for us would be triggered. Consequently, if other generic versions of Lovenox are approved and commercialized, our revenues from 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.

Patent litigation with Teva Pharmaceutical Industries Ltd., the innovator of Copaxone, may cause delays and additional expense in the commercialization of M356. If we are not successful in commercializing M356 or are significantly delayed in doing so, our business may be materially harmed.

In July 2008, the FDA accepted for review the ANDA for generic Copaxone submitted by Sandoz. In response, Teva Pharmaceutical Industries Ltd. has publicly stated its intent to bring a patent infringement claim against us as well as Sandoz. Litigation could significantly delay, impair or prevent our ability to commercialize M356 and our business could be materially harmed. Litigation involves many risks and uncertainties, and there is no assurance that Sandoz or we will prevail in any lawsuit with Teva Pharmaceutical Industries. In addition, Teva Pharmaceutical Industries has significant resources and any litigation with Teva Pharmaceutical Industries could last a number of years, potentially delaying or prohibiting the commercialization of M356.

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 or M356, 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.

The basis for approval of some of our products in current or future development, including M-Enoxaparin and M356, is new technologies that have not previously been accepted by the FDA or other regulatory authorities. 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 or our collaborative partners are unable to obtain sufficient quantities of raw materials, experience manufacturing difficulties or are unable to manufacture sufficient quantities of our product candidates, including M-Enoxaparin and M118, 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 our collaborative partners and other third parties to provide raw materials, manufacture the drug substance, produce the final drug product and provide certain analytical services with respect to our product candidates, including M-Enoxaparin. We, our collaborative partners 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, in early 2008, a contaminant was identified in some supplies of unfractionated heparin, or UFH. UFH is a starting material for some of our product candidates, and therefore this event may have an adverse impact on the supply of starting materials for some of our product candidates and we, our collaborative partners or our third -party contractors may have difficulty producing products in the quantities necessary to meet FDA requirements or meet anticipated market demand. If we, our collaborative partners or our third-party manufacturers or suppliers are unable to satisfy the FDA pre-approval manufacturing requirements for our product candidates, or are unable to produce our products 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.

If the raw materials, including UFH, used in our products become difficult to obtain, significantly increase in cost or become unavailable, we may be unable to produce our products and this would have a material adverse impact on our business.

We and our collaborative partners and vendors obtain certain raw materials, including UFH, from suppliers who in turn source the materials from other countries. The FDA has recently placed restrictions on the import of some raw materials from China and imposed testing requirements, and may in the future place additional restrictions and testing requirements, on the use of raw materials, including UFH, in products intended for sale in the United States, including our M-Enoxaparin, M118 and other products. As a result, the raw materials, including UFH, used in our products may become difficult to obtain, significantly increase in cost, or become unavailable to us. If any of these events occur, we may be unable to produce our products in sufficient quantities to meet the requirements for the commercial launch of the product or to meet future demand, which would have a material adverse impact on 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 June 30, 2008, we had cash, cash equivalents and marketable securities totaling $109.4 million. For the six months ended June 30, 2008, we had a net loss of $28.3 million and used cash in operating activities of $24.3 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, preclinical testing and clinical trials of our drug candidates, as well as funds necessary to manufacture and market any products that are approved for commercial sale. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development.

Our future capital requirements may vary depending on the following:

- the advancement of our generic product candidates and other development programs;
- the timing of FDA approval of the products of our competitors;

- the cost of litigation, including potential patent litigation with Sanofi-Aventis relating to Lovenox or Teva Pharmaceuticals Industries relating to Copaxone that, in either case, 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 third parties 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. Any additional capital raised through the sale of equity may dilute your percentage ownership of our common stock. Capital raised through debt financing would require us to make periodic interest payments and may impose potentially restrictive covenants on the conduct of our business. 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.

We will need to develop or acquire additional technologies as part of our efforts to analyze the chemical composition of complex mixture drugs.

In order to adequately analyze other complex mixture drugs, 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 could reduce the likelihood of our success developing additional 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, conducting preclinical studies, 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, distribution and sales capabilities;
- the effectiveness of our marketing, distribution 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, distribution 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.

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

We are dependent on the members of our 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, 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 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, including M-Enoxaparin and M356, as therapeutic equivalents to their corresponding reference listed drugs, 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, such as M-Enoxaparin and M356. We will be required to demonstrate to the satisfaction of the FDA, among other things, that our generic products (i) contain the same active ingredients as the branded products upon which they are based, (ii) are of the same dosage form, strength and route of administration as the branded products upon which they are based, and have the same labeling as the approved labeling for the branded products, with certain exceptions, and (iii) meet compendial or other applicable standards for strength, quality, purity and identity, including potency. In addition, approval of a generic product generally requires demonstrating that the generic drug is bioequivalent to the listed drug upon which it is based, meaning 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. However, the FDA may or may not waive the requirements for certain bioequivalence data (including clinical data) for certain drug products, including injectable solutions that have been shown to contain the same active and inactive ingredients in the same concentration as the reference listed drug.

Determination of therapeutic equivalence of our generic versions of complex drugs to the reference listed drugs will be based, in part, on our demonstration of chemical equivalence of our version 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. In that case, the FDA may require additional information, including preclinical or clinical test results, to determine therapeutic equivalence or to confirm that any inactive ingredients or impurities do not compromise the product's safety and efficacy. Provision of sufficient information for approval may be difficult, expensive and lengthy. 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, Copaxone 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 complete other lengthy procedures, the commercialization of some of our development candidates could be delayed or prevented or become more expensive. 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 United States Congress does not take action to create an abbreviated regulatory pathway for follow-on biologics, and if the FDA is not able to establish specific guidelines regarding the scientific analyses required for characterizing follow-on versions of biologics and complex protein drugs, then the uncertainty about the potential value of our glycoprotein program will be increased.

The regulatory climate in the United States for follow-on versions of biologics and complex protein products 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 biologics and most protein drugs. The FDA has approved the majority of new protein products under the Public Health Service Act, or PHSA, through the use of Biologic License Applications, or BLAs. There is no provision in the PHSA for an abbreviated BLA approval pathway comparable to an ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, 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 under Section 505(b) of the FDCA, there is uncertainty as to what data the FDA may require to demonstrate the sameness required for approval of an ANDA. 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(b)(1) 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 United States Congress to enact legislation establishing an abbreviated pathway for approval of follow-on biologics 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 studies 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 studies and clinical trials 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 our product candidates may have other unexpected characteristics.

The results from preclinical studies 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 vary 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.

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.

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;
- 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, Sanofi-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 Sanofi-Aventis Citizen Petition, and Sanofi-Aventis has filed numerous supplements and reply comments in support of its Citizen Petition. The FDA has yet to rule on the Sanofi-Aventis Citizen Petition, and if the FDA ultimately grants the Sanofi-Aventis Citizen 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.

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 from time to time considered other 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 have removed 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 reimbursement we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition.

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, 2007, 2006 and 2005, we spent approximately $64,000, $31,000 and $19,000, 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.

Third parties may allege that we are infringing their intellectual property rights, 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 asserts that we are infringing their intellectual property rights or that our creation or use of proprietary technology infringes upon their intellectual property rights, we might be forced to incur expenses to respond to and litigate the claims. Furthermore, we may be ordered to pay damages, potentially including treble damages, if we are found to have willfully infringed a party's 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 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 to determine or enforce our intellectual property rights, we could incur substantial costs which could adversely affect our business.

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. 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 the 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 if 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 the 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 worldwide 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 commercialization of M-Enoxaparin, 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 collaboration and license agreement, or Definitive Agreement, we executed with Sandoz in June 2007, as amended in April 2008, 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 either party's 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 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 manufacturing, sales, marketing and distribution, we may need to enter into alliances or collaborations with other companies that can assist with the development and commercialization of our drug candidates. In those situations, we would expect our alliance or collaborative partners to provide substantial capabilities in manufacturing, sales, marketing and distribution. 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.

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 particular drug candidates 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.

We and our collaborative partners 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 collaborative 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 these 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 these 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. We cannot be certain that we will be able to obtain and/or maintain long-term supply and 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 current Good Manufacturing Practices, or cGMP, regulations. Any failure by us, our collaborative partners 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.

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 33.5% of our outstanding common stock as of June 30, 2008. 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 our 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 has 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 or M356 ANDA or other adverse FDA decisions relating to M-Enoxaparin or M356, including the FDA requiring clinical trials as a condition to M-Enoxaparin or M356 approval;
- FDA approval of other ANDAs for generic versions of Lovenox or Copaxone;
- litigation involving our company or our general industry or both;
- a decision in favor of or against Sanofi-Aventis in any of the current patent litigation matters, or a settlement related to any of those cases;
- failure of our other product applications to meet the requirements for regulatory review and/or approval;
- 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;
- demonstration of or failure to demonstrate the safety and efficacy for our novel development product candidates;
- our inability to manufacture any products in conformance with cGMP or in commercial quantities;
- 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.

We could be subject to class action litigation due to stock price volatility, which, if it occurs, will distract our management and could result in substantial costs or large judgments against us.

The stock market in general has recently experienced extreme price and volume fluctuations. In addition, the market prices of securities of companies in the biotechnology industry have been extremely volatile and have experienced fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These fluctuations could adversely affect the market price of our common stock. In the past, securities class action litigation has often been brought against companies following periods of volatility in the market prices of their securities. We may be the target of similar litigation in the future. Securities litigation could result in substantial costs and divert our management's attention and resources, which could cause serious harm to our business, operating results and financial condition.

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

Our Annual Meeting of Stockholders was held on June 4, 2008.

There were present at the Annual Meeting in person or by proxy stockholders holding an aggregate of 26,942,746 shares of common stock. The results of the vote taken at the Annual Meeting with respect to the election of the nominees to serve as Class I directors were as follows:

Class III Director Nominees	For	Withheld
Alan Crane	25,751,546 shares	1,191,200 shares
Peter Barton Hutt	23,694,895 shares	3,247,851 shares
Marsha H. Fanucci	26,056,217 shares	886,529 shares

Mr. Crane, Mr. Hutt and Ms. Fanucci were each elected to serve for a three-year term of office or until their successors are duly elected and qualified. John K. Clarke, Robert S. Langer, Jr., James Sulat and Craig A. Wheeler are currently serving as Class II Directors and Peter Barrett, Ram Sasisekharan, Bennett M. Shapiro and Elizabeth Stoner are currently serving as Class III Directors.

In addition, a vote of the stockholders was taken at the Annual Meeting with respect to the proposal to ratify the selection by our Audit Committee of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2008. Of the 26,942,746 shares of common stock present at the Annual Meeting, 26,905,896 shares voted in favor of such proposal, 26,175 shares were voted against such proposal and 10,674 shares abstained from voting.

Item 6. Exhibits.

10.1	Form of Amendment to Employment Agreement, dated May 28, 2008, by and between the Registrant and each of John E. Bishop and James Roach.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

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

Momenta Pharmaceuticals, Inc.

Date: August 5, 2008

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

Date: August 5, 2008

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

Exhibit 10.1

AMENDMENT NO. 1 TO
EMPLOYMENT AGREEMENT

THIS AMENDMENT NO. 1 made as of May , 2008 amends the EMPLOYMENT AGREEMENT (the "Agreement") dated April 28, 2008 by and between by Momenta Pharmaceuticals, Inc., a Delaware corporation with its principal place of business at 675 West Kendall Street, Cambridge, Massachusetts (the "Company"), and (the "Employee"). Any capitalized terms used herein but not defined shall have the meaning ascribed to such term in the Agreement.

Momenta and the Employee desire to amend the Agreement to reflect mutually agreed upon revised terms in accordance with the provisions of this Amendment. In consideration of the mutual covenants and agreements set forth herein and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Momenta and the Employee agree as follows:

1. The following new Section 6.3 shall be inserted into the Agreement:

6.3 Disputes.

(a) Settlement of Disputes; Arbitration . All claims by the Employee for benefits under this Section 6 shall be directed to and determined by the Board of Directors of the Company and shall be in writing. Any denial by the Board of Directors of a claim for benefits under this Section 6 shall be delivered to the Employee in writing and shall set forth the specific reasons for the denial and the specific provisions of this Agreement relied upon. The Board of Directors shall afford a reasonable opportunity to the Employee for a review of the decision denying a claim. Any further dispute or controversy arising under or in connection with this Section 6 shall be settled exclusively by arbitration in Boston, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction.

(b) Expenses . The Company agrees to pay as incurred, to the full extent permitted by law, all legal, accounting and other fees and expenses which the Employee may reasonably incur as a result of any claim or contest (regardless of the outcome thereof) by the Company, the Employee or others regarding the validity or enforceability of, or liability under, any provision of this Section 6 or any guarantee of performance thereof (including as a result of any contest by the Employee regarding the amount of any payment or benefits pursuant to this Section 6), plus in each case interest on any delayed payment at the applicable Federal rate provided for in Section 7872(f)(2)(A) of the Code.

2. The current Section 6.3 ("Injunctive Relief") shall be renumbered to Section 6.4.

Except as expressly amended by this Amendment, the provisions of the Agreement shall remain in full force and effect.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year set forth above.

MOMENTA PHARMACEUTICALS, INC.

By: _____

Title: _____

EMPLOYEE

_____
Name

EXHIBIT 31.1

CERTIFICATION

I, Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals, Inc., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Craig A. Wheeler

Dated: August 5, 2008

Craig A. Wheeler
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

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

1. I have reviewed this Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Richard P. Shea

Dated: August 5, 2008

Richard P. Shea
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Craig A. Wheeler, President and Chief Executive Officer of the Company, and Richard P. Shea, Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Craig A. Wheeler

Dated: August 5, 2008

Craig A. Wheeler
President and Chief Executive Officer

/s/ Richard P. Shea

Dated: August 5, 2008

Richard P. Shea
Chief Financial Officer