MOMENTA PHARMACEUTICALS INC
Form 10-Q
August 09, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2006

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 000-50797

Momenta Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3561634**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
675 West Kendall Street, Cambridge, MA	**02142**
(Address of Principal Executive Offices)	(Zip Code)

(617) 491-9700

(Registrant s Telephone Number, Including Area Code)

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

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

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

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

Indicate the number of shares outstanding of each of the Registrant s classes of Common Stock as of August 1, 2006.

Class	**Number of Shares**
Common Stock $0.0001 par value	31,223,060

MOMENTA PHARMACEUTICALS, INC.
TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited).

MOMENTA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)
(unaudited)

	June 30, 2006	December 31, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 40,691	$ 25,890
Marketable securities	99,161	130,364
Unbilled collaboration revenue	5,727	4,347
Prepaid expenses and other current assets	5,149	2,799
Total current assets	150,728	163,400
Property and equipment, net of accumulated depreciation	10,274	5,917
Restricted cash	1,778	1,778
Other assets	1	6
Total assets	$ 162,781	$ 171,101
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 9,132	$ 3,080
Accrued expenses	2,801	3,355
Deferred revenue	147	147
Line of credit obligations	845	845
Capital lease obligations	552	284
Current portion of lease financing liability	547	
Deferred rent	70	28
Total current liabilities	14,094	7,739
Deferred revenue, net of current portion	49	123
Line of credit obligation, net of current portion	1,189	1,621
Capital lease obligations, net of current portion	2,429	1,375
Deferred rent, net of current portion	268	88
Lease financing liability, net of current portion	2,569	
Total liabilities	20,598	10,946
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.01 par value; 5,000 shares authorized at June 30, 2006 and December 31, 2005, 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, 31,170 and 30,465 shares issued and outstanding at June 30, 2006 and December 31, 2005, respectively	3	3
Additional paid-in capital	239,819	236,190
Deferred compensation		(2,193)
Accumulated other comprehensive loss	(117)	(239)
Accumulated deficit	(97,522)	(73,606)

Total stockholders equity		142,183		160,155
Total liabilities and stockholders equity	$	162,781	$	171,101

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

MOMENTA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	**2005**	**2006**	**2005**
Collaboration revenue	$ 5,397	$ 3,364	$ 7,904	$ 6,779
Operating expenses:				
Research and development*	13,471	4,999	22,916	9,930
General and administrative*	6,094	3,231	12,061	5,771
Total operating expenses	19,565	8,230	34,977	15,701
Loss from operations	(14,168)	(4,866)	(27,073)	(8,922)
Other income (expense):				
Interest income	1,680	320	3,337	633
Interest expense	(96)	(34)	(180)	(61)
Net loss attributable to common stockholders	$ (12,584)	$ (4,580)	$ (23,916)	$ (8,350)
Basic and diluted net loss per share attributable to common stockholders	$ (0.41)	$ (0.18)	$ (0.78)	$ (0.33)
Shares used in computing basic and diluted net loss per share attributable to common stockholders	30,532	25,116	30,488	24,992

*Includes the following stock-based compensation expense:

Research and development	$ 1,382	$ 157	$ 2,144	$ 271
General and administrative	1,608	418	3,257	731
Total stock-based compensation	$ 2,990	$ 575	$ 5,401	$ 1,002

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

MOMENTA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2006	**2005**
Operating activities:		
Net loss	$ (23,916)	$ (8,350)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation and amortization	681	464
Stock compensation expense	5,401	1,002
Deferred rent	222	
Gain on disposal of assets	(4)	
Noncash interest expense		5
Amortization of premium on investments	352	662
Changes in operating assets and liabilities:		
Accounts receivable		2,238
Unbilled collaboration revenue	(1,380)	(1,414)
Prepaid expenses and other current assets	(430)	(282)
Other assets	5	1
Accounts payable	6,052	(485)
Accrued expenses	(554)	639
Deferred revenue	(74)	(74)
Net cash used in operating activities	(13,645)	(5,594)
Investing activities:		
Purchases of property and equipment	(5,034)	(1,673)
Purchases of marketable securities	(47,705)	(27,624)
Maturities of marketable securities	78,678	29,932
Net cash provided by investing activities	25,939	635
Financing activities:		
Proceeds from financing of leasehold improvements	1,196	
Proceeds from capital lease obligations	1,322	
Proceeds from line of credit		1,345
Principal payments on line of credit	(432)	(362)
Payment of officer obligation		36
Proceeds from issuance of common stock	421	116
Net cash provided by financing activities	2,507	1,135
Net increase (decrease) in cash and cash equivalents	14,801	(3,824)
Cash and cash equivalents at beginning of period	25,890	11,678
Cash and cash equivalents at end of period	$ 40,691	$ 7,854

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

MOMENTA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED UNAUDITED FINANCIAL STATEMENTS

1. The Company

Business

Momenta Pharmaceuticals, Inc. (the Company or Momenta) was incorporated in the state of Delaware on May 17, 2001. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the detailed structural analysis and design of complex sugars for the development of technology-enabled generic versions of complex drug products, improved versions of existing drugs, and the discovery of novel drugs and new biological processes.

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

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting only of normal recurring accruals, considered necessary for a fair presentation of the results of these interim periods have been included. The results of operations for the six months ended June 30, 2006 are not necessarily indicative of the results that may be expected for the full year. These unaudited financial statements should be read in conjunction with the audited financial statements and related notes thereto included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2005, which was filed with the Securities and Exchange Commission (SEC) on March 16, 2006.

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.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The Company s consolidated financial statements include the Company s accounts and the accounts of the Company s wholly-owned subsidiary, Momenta Pharmaceuticals Securities Corporation. All inter-company transactions have been eliminated.

Reclassifications

Certain prior year amounts in the collaboration revenue and research and development expenses of the consolidated statements of operations have been reclassified to conform to the current year presentation. This reclassification has no impact on previously reported net loss attributable to common stockholders.

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 debt securities at the time of purchase and evaluates such designation as of each balance sheet date. Unrealized gains and losses are included in accumulated other comprehensive loss and reported as a separate component of stockholders equity. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. Interest earned on marketable securities is included in interest income.

Credit Risks and Concentrations

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

Fair Value of Financial Instruments

The carrying amounts of the Company s financial instruments, which include cash equivalents and other accrued expenses, approximate their fair values due to their short maturities. The carrying amount of the Company s line of credit and capital lease obligations approximates their fair values due to their variable interest rates.

Unbilled Collaboration Revenue

Unbilled collaboration revenue represents an amount owed from one collaborative partner at June 30, 2006 and December 31, 2005. The Company has not recorded any bad debt write-offs and it monitors its receivables closely to facilitate timely payment.

Property and Equipment

Property and equipment are stated at cost. Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets are charged to expense. Upon disposal, the related cost and accumulated depreciation or amortization are removed from the accounts and any resulting gain or loss is included in the results of operations. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. Leased assets meeting certain capital lease criteria are capitalized and the present value of the related lease payments is recorded as a liability. Assets under capital lease arrangements are depreciated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the estimated useful lives of the assets or related lease terms, whichever is shorter.

Long-Lived Assets

The Company evaluates the recoverability of its property and equipment 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. SFAS 144 further refines the requirements of SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of, such that companies

(1) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (2) measure an impairment loss as the difference between the carrying amount and fair value of the asset. Impairment is measured based on the difference between the carrying value of the related assets or businesses and the undiscounted future cash flows of such assets or businesses. In addition, SFAS 144 provides guidance on accounting and disclosure issues surrounding long-lived assets to be disposed of by sale. No impairment charges have been required to be recognized through June 30, 2006.

Revenue Recognition

Revenues associated with the Company s 2003 collaboration (the 2003 Sandoz Collaboration) with Sandoz N.V. and Sandoz Inc. ("Sandoz") include an initial payment, reimbursement of development services and expenses, and potential future milestones and royalties. The initial payment represented reimbursement of specific development costs incurred prior to the date of the collaboration. Amounts earned under the collaboration agreement are not refundable if the research or development is unsuccessful. To date, the Company has not earned any milestones or royalties under the collaboration agreement.

The Company uses revenue recognition criteria outlined in Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition, and Emerging Issues Task Force (EITF) Issue 00-21, Revenue Arrangements with Multiple Deliverables, or EITF 00-21. Accordingly, revenues from licensing agreements are recognized based on the performance requirements of the agreement. Non-refundable up-front fees, where the Company has an ongoing involvement or performance obligation, are recorded as deferred revenue in the balance sheet and amortized into collaboration revenue in the statement of operations over the term of the performance obligation. Revenues from research and development services and expenses are recognized in the period the services are performed and the reimbursable costs are incurred.

Research and Development

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

Stock-Based Compensation

The Company s 2002 Stock Incentive Plan, as amended, provides for the granting of stock options to purchase the Company s common stock and restricted stock to employees, officers, directors, consultants and advisors. Options granted under the 2002 Stock Incentive Plan may be incentive stock options or nonstatutory stock options under the applicable provisions of the Internal Revenue Code. Since the effective date of the 2004 Stock Incentive Plan, as amended, described below, the Company no longer grants options under the 2002 Stock Incentive Plan. Any authorized and ungranted shares, and unvested shares granted under the 2002 Stock Incentive Plan that are returned to the Company as a result of terminations will subsequently lapse.

Pursuant to the terms of the Company s 2004 Stock Incentive Plan, as amended, (the Incentive Plan), the Company is authorized to issue up to 3,948,785 shares of common stock with annual increases (to be added on the first day of the Company s fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013) 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. The Company s Board of Directors elected not to increase the number of authorized shares related to the Incentive Plan for 2005 and 2006.

Incentive Stock Options are granted only to employees of the Company. Incentive Stock Options granted to employees who own more than 10% of the total combined voting power of all classes of stock

will be granted at no less than 110% of the fair market value of the Company s common stock on the date of grant. Non-statutory stock options may be granted to employees, officers, directors, consultants and advisors. Incentive stock options generally vest ratably over four years. Non-statutory stock options granted have varying vesting schedules. The options generally expire ten years after the date of grant.

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS No. 123(R), *Share-Based Payment*, or SFAS 123R, using the modified prospective method. Under that method, compensation cost recognized in the six months ended June 30, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123, or SFAS 123, *Accounting for Stock-Based Compensation*, and (b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. In accordance with SFAS 123R, the estimated grant date fair value of each stock-based award is recognized as expense on a ratable basis over the requisite service period (generally the vesting period). Results for prior periods have not been restated.

Total compensation cost for all share-based payment arrangements for the three months ended June 30, 2006 and 2005 was $3.0 million and $0.6 million, respectively. Total compensation cost for all share-based payment arrangements for the six months ended June 30, 2006 and 2005 was $5.4 million and $1.0 million, respectively. The increase in 2006 is primarily attributable to the adoption of SFAS 123R in the first quarter of 2006 using the modified prospective transition method. The adoption of SFAS 123R on January 1, 2006 resulted in the recognition of stock-based compensation expense of $3.0 million, an increase in net loss attributable to common stockholders of $3.0 million and an increase in basic and diluted net loss per share allocable to common stockholders of $0.10 per share. The Company additionally reclassified its unearned compensation on non-vested share awards of $2.2 million at December 31, 2005 to additional paid-in capital.

Prior to January 1, 2006, the Company accounted for stock based compensation plans under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related interpretations, as permitted by SFAS 123. In accordance with APB 25, cost for stock-based compensation was recognized as expense based on the excess, if any, of the quoted market price of the stock at the grant date of the award or other measurement date over the amount an employee must pay to acquire the stock. In prior years, certain grants of stock options and stock awards were made at exercise prices deemed to be less than the fair value of the Company s common stock and, as a result, the Company recorded stock-based compensation expense. Non-vested share awards were recorded as compensation cost over the requisite service periods based on the market value on the date of grant.

The following table illustrates the effect on fiscal 2005 net loss attributable to common stockholders and net loss per share allocable to common stockholders if the Company had applied the fair value recognition provisions of SFAS 123 to options granted under the Company s stock option plans.

	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
Net loss attributable to common stockholders as reported	$ (4,580)	$ (8,350)
Add: Stock-based employee compensation expense included in reported net loss attributable to common stockholders	350	699
Deduct: Total stock-based employee compensation expense determined under fair value method for all awards	(506)	(884)
Pro forma net loss	$ (4,736)	$ (8,535)
Basic and diluted net loss per share allocable to common stockholders:		
As reported	$ (0.18)	$ (0.33)
Pro forma net loss	$ (0.19)	$ (0.34)

For purposes of this pro forma disclosure, the value of the options is estimated using the Black-Scholes-Merton option-pricing formula and amortized to expense on a straight-lined basis over the options vesting periods using the following assumptions:

	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
Expected volatility	80%	80%
Expected dividends		
Expected term (in years)	6	6
Risk-free rate	4.0%	4.0%

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 that uses the assumptions noted in the table below. Because of the Company s limited history as a publicly-traded company, to estimate expected volatility the Company used a 50/50 blend of its own historic and implied volatility and an average of historic and implied volatilities of similar entities. For purposes of identifying similar entities, the Company considered characteristics such as industry, stage of life cycle, and financial leverage. The expected term of options granted is derived from the average midpoint between vesting and the contractual term, as described in SEC s Staff Accounting Bulletin No. 107, *Share-Based Payment*. In the future, as information regarding post vesting termination becomes more accessible, the Company may change its method of deriving the expected term. This change could impact the Company s fair value of options granted in the future. The Company expects to refine its method of deriving expected term no later than January 1, 2008. The risk-free rate for the expected term of the option is based on the U.S. Treasury yield curve in effect at the time of grant.

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

The Company estimated the fair values using the following weighted average assumptions:

	Three Months Ended June 30, 2006	Six Months Ended June 30, 2006
Expected volatility	68%	71%
Expected dividends		
Expected term (in years)	6	6
Risk-free rate	5.1%	4.8%

The following table summarizes all stock option plan activity for the six months ended June 30, 2006:

	Number of Stock Options (in thousands)	Weighted average exercise price	Weighted average remaining life in yrs	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2006	1,967	$ 7.62		
Granted	648	18.31		
Exercised	(53)	5.43		
Forfeited	(33)	13.41		
Outstanding at June 30, 2006	2,529	$ 10.33	8.37	$ 12,577
Exercisable at June 30, 2006	1,075	$ 5.63	7.70	$ 8,142

The weighted average grant date fair value of options granted during the three months ended June 30, 2006 and 2005 was $8.52 and $8.09 per option, respectively. The weighted average grant date fair value of options granted during the six months ended June 30, 2006 and 2005 was $12.22 and $7.33 per option, respectively. The total intrinsic value of options exercised during the three months ended June 30, 2006 and 2005 was $0.1 million and $0.3 million, respectively. The total intrinsic value of options exercised during the six months ended June 30, 2006 and 2005 was $0.9 million and $0.9 million, respectively. At June 30, 2006, the total unrecognized compensation cost related to nonvested stock options was $12.0 million. The cost is expected to be recognized over a weighted average period of 2.5 years. The fair value of shares vested during the three months ended June 30, 2006 and 2005 was $3.3 million and $0.4 million, respectively. The fair value of shares vested during the six months ended June 30, 2006 and 2005 was $4.1 million and $0.7 million, respectively.

Cash received from option exercises for the three months ended June 30, 2006 and 2005 was $0.1 million and $18,000, respectively. Cash received from option exercises for the six months ended June 30, 2006 and 2005 was $0.3 million and $0.1 million, respectively. Due to the Company s net loss position, the tax benefit related to the tax deductions from option exercises was not realized in any of the periods presented.

Restricted Stock Grants

During 2002, the Company entered into Restricted Stock Purchase Agreements with two officers and a non-employee to purchase an aggregate of 1,101,870 shares of common stock. Pursuant to one of the Restricted Stock Purchase Agreements, 980,859 shares of common stock were sold to an officer for $106,662. The purchase price was payable ratably over approximately three years with the final payment made during the first quarter of 2005. Each Restricted Stock Purchase Agreement provides for the repurchase of common stock by the Company at a price equal to the original price paid, adjustable for certain dilutive events, until the shares vest. The repurchase provisions generally lapse over a three to four year period provided that each recipient subject to such agreements continues service with the Company. At June 30, 2006 and December 31, 2005, respectively, there were no shares and 64,967 shares, respectively, of unvested restricted common stock outstanding under these agreements.

On March 7, 2006, the Company entered into new Restricted Stock Purchase Agreements with certain executive officers and an employee to purchase an aggregate of 630,000 shares of common stock. Each of these restricted stock grants were made under the Incentive Plan, with the following vesting provisions: (i) one half of the shares of common stock vest and become free from forfeiture provisions and transfer restrictions on the fourth anniversary of the grant date (i.e., March 7, 2010) and (ii) one half of the shares of common stock vest and become free from forfeiture provisions and transfer restrictions upon the commercial launch of M-Enoxaparin in the United States by the Company (or any of the Company s partners or collaborators), provided that such commercial launch occurs on or before March 7, 2011. In each case, the shares of common stock issued pursuant to each restricted stock agreement described above will only vest if the recipient is an employee of the Company as of the applicable vesting date.

The fair value of the restricted stock for the agreements entered into in March 2006 is the market price of common stock at the date of grant, which is amortized to compensation expense over the explicit and implicit service periods.

Changes in the Company s restricted stock for the six months ended June 30, 2006 were as follows

	(in thousands except per share amounts):		
	Restricted Shares		Weighted-average grant date fair value
Nonvested restricted stock at January 1, 2006	65	$	1.87
Granted	630		23.62
Vested	65		1.87
Nonvested restricted stock at June 30, 2006	630	$	23.62

The Company recorded stock-based compensation expense of $1.6 million and $0.1 million related to outstanding restricted stock grants during the three months ended June 30, 2006 and 2005, respectively. The Company recorded stock-based compensation expense of $2.2 million and $0.2 million related to outstanding restricted stock grants during the six months ended June 30, 2006 and 2005, respectively. As of June 30, 2006, there was $12.7 million of unrecognized compensation cost related to nonvested restricted stock arrangements. The cost is expected to be recognized over a weighted average period of 2.5 years. The total fair value of shares vested during the three months ended June 30, 2006 and 2005 was $0 and $0.1 million, respectively. The total fair value of shares vested during the six months ended June 30, 2006 and 2005 was $0.1 million and $0.2 million, respectively.

Common Stock Options to Consultants

As of June 30, 2006, the Company had granted options to purchase 141,162 shares of common stock to consultants, 35,800 of which were granted to two individuals who were previously and continue to be members of the Board of Directors and 4,562 of which were granted to one individual who was a consultant prior to becoming a member of the Board, but who is no longer a consultant. Of the total shares granted, 25,598 were exercised and not subject to repurchase, and 19,782 were unvested. These options were granted in exchange for consulting services to be rendered and vest over periods of up to four years. The Company reversed compensation expense for stock options granted to consultants of $0.1 million during the three months ended June 30, 2006 due to the decrease in the Company s share price. The Company recorded a charge to operations for stock options granted to consultants using the graded-vesting method of $0.2 million during the three months ended June 30, 2005. The Company recorded charges to operations for stock options granted to consultants using the graded-vesting method of $0.2 million and $0.3 million during the six months ended June 30, 2006 and 2005, respectively.

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

Employee Stock Purchase Plan

The Company s 2004 Employee Stock Purchase Plan (the Purchase Plan) became effective on June 25, 2004, the closing date of the Company s initial public offering. Under the Purchase Plan, participating employees purchase common stock through payroll deductions. An employee may withdraw from an offering before the purchase date and obtain a refund of the amounts withheld through payroll deductions. The purchase price is equal to 85% of the lower of the closing price of the Company s common stock on the first business day and the last business day of the relevant plan period. The first

plan period began on June 25, 2004 and ended on January 31, 2005. The second plan period began on February 1, 2005 and ended on January 31, 2006 (the 2005 Offering). In February 2006, the Purchase Plan was amended to provide for two 6-month plan periods, the first plan period from February 1, 2006 through July 31, 2006 (the First 2006 Offering) and the second from August 1, 2006 through January 31, 2007.

The purchase price for the 2005 Offering was $5.85 and 23,057 shares of common stock were issued in January 2006 under the Purchase Plan. The purchase price for the First 2006 offering was $14.73 and 11,770 shares of common stock were issued in July 2006 under the Purchase Plan. During the three months ended June 30, 2006, the Company recorded stock-based compensation expense of approximately $0.1 million related to the First 2006 Offering. During the six months ended June 30, 2006, the Company recorded stock-based compensation expense of approximately $0.1 million related to the 2005 and First 2006 Offering.

The fair value of the offerings was estimated on the date of grant using the Black-Scholes-Merton option-pricing model that uses the assumptions noted in the following table. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant.

	First 2006 Offering	2005 Offering
Risk-free interest rate	4.6%	2.9%
Expected volatility	73%	80%
Expected life	6 months	1 year
Expected dividend		

Income Taxes

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

Comprehensive Loss

The Company reports comprehensive loss in accordance with SFAS No. 130, *Reporting Comprehensive Income*, or SFAS 130. SFAS 130 establishes rules for the reporting and display of comprehensive loss and its components. Accumulated other comprehensive loss as of June 30, 2006 and June 30, 2005 consists entirely of unrealized losses on available-for-sale securities. Comprehensive loss for the three months ended June 30, 2006 and 2005 was $12.5 million and $4.5 million, respectively. Comprehensive loss for the six months ended June 30, 2006 and 2005 was $23.8 million and $8.3 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 available to common stockholders 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 available to common stockholders by the weighted-average number of common shares and dilutive common share equivalents then outstanding. Potential common stock equivalent shares consist of the incremental common shares issuable upon the conversion of preferred stock, shares issuable upon the exercise of stock options and upon the exercise of warrants. Since the Company has a net loss for all

periods presented, the effect of all potentially dilutive securities is antidilutive. Accordingly, basic and diluted net loss per share is the same.

Segment Reporting

The Company has adopted SFAS No. 131, *Disclosure About Segments of an Enterprise and Related Information*, which requires companies to report selected information about operating segments, as well as 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, 2006 have come from one collaborative partner.

Commitments and Contingencies

The Company leases office space and equipment under various operating lease agreements. In September 2004 the Company entered into an agreement to sublease 53,323 square feet of office and laboratory space for a term of 80 months. The Company has an option to extend the sublease for one additional term of 48 months ending April 2015 or on such other earlier date as provided in accordance with the sublease agreement.

In November 2005, the Company amended its sublease agreement to sublease an additional 25,131 square feet in its current premises through April 2011. Under the lease amendment the sublandlord agreed to finance the leasehold improvements. In accordance with Financial Accounting Standards Board (FASB) Staff Position (FSP) 13-1, *Accounting for Rental Costs Incurred during a Construction Period*, the Company commenced expensing the applicable rent during the construction period, which was completed in June 2006. In accordance with EITF 97-10, *The Effect of Lessee Involvement in Asset Construction*, at June 30, 2006, the Company has recorded $3.1 million in leasehold improvements, $3.1 million as a related lease financing liability and $1.9 million as a reimbursement receivable from the sublandlord.

In July 2006, the Company signed a non-binding letter of intent to sublease approximately 22,700 square feet of additional laboratory and office space in another building, with a term of 49 months through April 2011.

In June 2006 and March 2006, the Company borrowed an additional $0.6 million and another $0.9 million, respectively, under its Master Lease Agreement (the Agreement) with General Electric Capital Corporation (GECC) and executed specified equipment schedules for laboratory, computer and office equipment. In June 2006 the Company and GECC agreed to increase the amount available to the Company under the Agreement to $3.2 million and as of June 30, 2006, the Company had drawn a total of $3.2 million against the Agreement. Borrowings under the Agreement are payable over a 54-month period at effective annual interest rates of 8.51-9.39%. In accordance with the Agreement, should the effective corporate income tax rate for calendar-year taxpayers increase above 35%, GECC will have the right to increase rent payments by requiring payment of a single additional sum, calculated in accordance with the Agreement. The Agreement also provides the Company an early purchase option after 48 months at a predetermined fair market value, which the Company intends to exercise. Under the Agreement, if any material adverse change in the Company or its business occurs, the total unpaid principal would become immediately due and payable. There have been no events of default. As of June 30, 2006, the Company had approximately $3.0 million in outstanding borrowings outstanding under the Agreement.

Subsequent Events

2006 Sandoz Collaboration

On July 25, 2006, the Company entered into a Stock Purchase Agreement, Memorandum of Understanding (MOU) and Investor Rights Agreement, collectively referred to as the 2006 Sandoz Collaboration. The details are as follows:

On July 25, 2006 the Company and Novartis Pharma AG, entered into a Stock Purchase Agreement pursuant to which Novartis Pharma AG has agreed to purchase 4,708,679 shares (the Shares), of the Company s common stock, representing approximately 13% of the Company s Common Stock expected to be outstanding after the closing, for $15.93 per Share, or an aggregate purchase price of $75,000,000. The closing of the purchase and sale of the Shares to Novartis Pharma AG is subject to customary closing conditions, including expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended. In connection with such closing, the MOU with respect to the collaboration executed between Sandoz AG (an affiliate of the Novartis Pharma AG)(Sandoz AG) and the Company on July 25, 2006 shall become effective.

In addition, on July 25, 2006, the Company and Novartis Pharma AG entered into an Investor Rights Agreement pursuant to which the Company has granted to Novartis Pharma AG certain registration rights and inspection rights, and Novartis Pharma AG has agreed to certain standstill obligations. Specifically, Novartis Pharma AG will be entitled to piggyback and demand registration rights under the Securities Act of 1933, as amended, with respect to the Shares.

The Company has also granted Novartis Pharma AG inspection rights whereby, subject to certain exceptions, Novartis Pharma AG may visit and inspect the Company s properties and records, discuss the Company s business and financial affairs with its officers, employees and other agents, and meet, at least twice a year, with the members of the Company s Board of Directors.

Novartis Pharma AG has agreed, until the earliest of (i) the termination of the MOU (or, if later entered into, a Collaboration and License Agreement between the parties), (ii) the Termination Date (as defined in the Investor Rights Agreement) and (iii) 24 months from the date of the closing of the purchase of the Shares, not to acquire any voting securities of the Company (other than an acquisition resulting in Novartis Pharma AG and its affiliates beneficially owning less than 13.5% of the total outstanding voting securities of the Company), make any public proposal for any merger, other business combination or other extraordinary transaction involving the Company, its securities or material assets or seek to control or influence the management, Board of Directors or policies of the Company, in each case subject to specified exceptions described in the Investor Rights Agreement.

The MOU will become effective on the closing of the purchase of the Shares. Under the terms of the MOU, the Company and Sandoz AG will exclusively collaborate on the development and commercialization of four 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. Sandoz AG has final decision-making authority with respect to certain development, regulatory and commercial decisions for certain products.

Costs will be borne by the parties in varying proportions, depending on the type of expense and the product. The Company is also eligible to receive up to $188 million in milestone payments if all milestones are achieved for the four product candidates. The parties will share profits in varying proportions, depending on the product, with the Company receiving fifty percent of the profits with respect to our M356 product.

Sandoz AG will indemnify the Company for various claims, and a certain portion of such costs may be offset against certain future payments received by the Company.

The MOU may be terminated if either party breaches the MOU or files for bankruptcy. In addition, the following termination rights apply to some of the products, on a product-by-product basis: (i) if

clinical trials are required, (ii) at Sandoz AG convenience within a certain time period, (iii) if the parties agree, or the relevant regulatory authority states in writing, that the Company s intellectual property does not contribute to product approval, or (iv) if Sandoz AG decides to permanently cease development and commercialization of a product.

The parties will negotiate the terms of a definitive Collaboration and License Agreement pursuant to the terms of the MOU, using commercially reasonable efforts to execute such definitive agreement within a specified period of time. The terms of the MOU will remain in effect until a definitive Collaboration and License Agreement is executed.

In addition, the Company and Sandoz AG may negotiate additional collaboration agreements with respect to other mutually selected products. Sandoz AG has the right to (i) select a certain number of these mutually selected products and (ii) negotiate expanded territories for certain products already part of the collaboration; for which, if the Company and Sandoz AG do not execute a definitive agreement within a specified time frame, the Company is permitted to enter into a transaction for such opportunity with a third party, provided that the terms which the Company gives to that third party can be no less favorable, taken as a whole, to the Company than the terms last offered to Sandoz AG. If the Company does not enter into a transaction with a third party in a specified time frame, then the negotiations between the Company and Sandoz AG with respect to such product will start again, with the corresponding rights and obligations if the parties do not execute a definitive agreement within the specified time frame.

Patent Infringement Litigation with Sanofi-Aventis

On August 8, 2006, the Company learned that Aventis Pharmaceuticals Inc. and Aventis Pharma S.A. (collectively, Sanofi-Aventis), the holder of the New Drug Application for Lovenox, initiated litigation against Sandoz relating to the paragraph IV certification contained in the amended ANDA filed by Sandoz seeking approval to market M-Enoxaparin in the United States.

Under the 2003 Sandoz Collaboration, Sandoz has agreed to indemnify the Company and the Company s collaborators involved in the M-Enoxaparin program, for any losses resulting from, among other things, any litigation by third parties, including Sanofi-Aventis, claiming that the manufacture, use or sale of injectable enoxaparin infringes any patents listed in the FDA s Orange Book for Lovenox. In the event that patent litigation expenses exceed a specified amount, Sandoz is permitted to offset a portion of the excess against profit-sharing amounts, royalties and the commercial milestone payments set forth in the 2003 Sandoz Collaboration. To the extent that any losses result from a third party claim for which the Company is obligated to indemnify Sandoz, Sandoz will have no obligation to indemnify the Company.

Recently Issued Accounting Standards

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections,* or SFAS 154, which replaces APB Opinion No. 20, *Accounting Changes*, or APB 20, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*, or SFAS 3. SFAS 154 provides guidance on the accounting for and the reporting of accounting changes, including changes in principle, accounting estimates and the reporting entity, as well as, corrections of errors in previously issued financial statements. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Many of the requirements of SFAS 154 are similar to or the same as those previously included in APB 20 and SFAS 3, however, SFAS 154 requires retrospective application of voluntary accounting changes (changes in accounting principle) to prior period financial statements unless it is impracticable to do so. SFAS 154 also provides that a change in accounting estimate that is affected by a change in accounting principle is accounted for as a change in estimate for purposes of applying SFAS 154. The Company adopted the provisions of SFAS 154 as of January 1, 2006. The Company does not currently believe that the adoption of this standard will result in a material effect on its financial position or results of operations.

In June 2006, the FASB issued FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes - An Interpretation of FASB Statement No. 109* , which clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. 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 and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 will be effective for fiscal years beginning after December 15, 2006. The Company has not yet completed its evaluation of the impact of adoption, but does not currently believe that adoption will have a material impact on its results of operations, financial position 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.

Business Overview

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

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

Our most advanced product candidate, M-Enoxaparin, is designed to be a technology-enabled generic version of Lovenox®, a widely prescribed low molecular weight heparin, or LMWH. In 2003, we formed a collaboration with Sandoz N.V. and Sandoz Inc., collectively Sandoz, affiliates of Novartis AG, to jointly develop, manufacture and commercialize M-Enoxaparin, or the 2003 Sandoz Collaboration. In accordance with our 2003 Sandoz Collaboration with Sandoz, an Abbreviated New Drug Application, or ANDA, was submitted to the FDA for M-Enoxaparin on August 29, 2005.

Our revenues for the six months ended June 30, 2006 were $7.9 million, consisting of amortization of the initial payment received under our 2003 Sandoz Collaboration and amounts earned by us for reimbursement by Sandoz of research and development services and reimbursement of development costs for M-Enoxaparin.

Since our inception in May 2001, we have incurred annual net losses. As of June 30, 2006, we had an accumulated deficit of $97.5 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 were derived from our 2003 Sandoz Collaboration and primarily consist of amounts earned by us for reimbursement by Sandoz of research and development services and development costs for M-Enoxaparin. On June 25, 2004, we completed an initial public offering of our 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.

To date, we have devoted substantially all of the expenditure of our capital resources to the research and development of our product candidates.

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

Significant Recent Developments

2006 Sandoz Collaboration

On July 25, 2006, we entered into a Stock Purchase Agreement, Memorandum of Understanding, or MOU, and Investor Rights Agreement with Novartis Pharma AG, collectively referred to as the 2006 Sandoz Collaboration. The details are as follows:

On July 25, 2006, we entered into a Stock Purchase Agreement with Novartis Pharma AG pursuant to which Novartis Pharma AG has agreed to purchase 4,708,679 shares of our common stock, representing approximately 13% of our common stock expected to be outstanding after the closing, for $15.93 per share, or an aggregate purchase price of $75,000,000. The closing of the purchase and sale of the shares of common stock to Novartis Pharma AG is subject to customary closing conditions, including expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended, or HSR. In connection with such closing, the MOU we executed with Sandoz AG on July 25, 2006 (as discussed below) shall become effective.

In addition, on July 25, 2006, we entered into an Investor Rights Agreement with Novartis Pharma AG pursuant to which we granted to Novartis Pharma AG certain registration rights and inspection rights, and Novartis Pharma AG has agreed to certain standstill obligations. Specifically, Novartis Pharma AG will be entitled to piggyback and demand registration rights under the Securities Act of 1933, as amended, with respect to the shares purchased under the Stock Purchase Agreement.

We also granted Novartis Pharma AG inspection rights whereby, subject to certain exceptions, Novartis Pharma AG may visit and inspect our properties and records, discuss our business and financial affairs with its officers, employees and other agents, and meet, at least twice a year, with the members of our Board of Directors.

Novartis Pharma AG has agreed, until the earliest of (i) the termination of the MOU (or, if later entered into, a Collaboration and License Agreement between the parties), (ii) the Termination Date (as defined in the Investor Rights Agreement) and (iii) 24 months from the date of the closing of the purchase of the Shares, not to acquire any of our voting securities (other than an acquisition resulting in Novartis Pharma AG and its affiliates beneficially owning less than 13.5% or our total outstanding voting securities), make any public proposal for any merger, other business combination or other extraordinary

transaction involving us, our securities or material assets or seek to control or influence our management, Board of Directors or policies, in each case subject to specified exceptions described in the Investor Rights Agreement.

The MOU will become effective on the closing of the purchase of the shares under the Stock Purchase Agreement. Under the terms of the MOU, we will exclusively collaborate with Sandoz AG on the development and commercialization of four 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. Sandoz AG has final decision-making authority with respect to certain development, regulatory and commercial decisions for certain products.

Costs will be borne by the parties in varying proportions, depending on the type of expense and the product. We are also eligible to receive up to $188 million in milestone payments if all milestones are achieved for the four product candidates. The parties will share profits in varying proportions, depending on the product, with our receiving fifty percent of the profits with respect to our M356 product.

Sandoz AG will indemnify us for various claims, and a certain portion of such costs may be offset against certain future payments received by us.

The MOU may be terminated if either party breaches the MOU or files for bankruptcy. In addition, the following termination rights apply to some of the products, on a product-by-product basis: (i) if clinical trials are required, (ii) at Sandoz AG 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, or (iv) if Sandoz AG decides to permanently cease development and commercialization of a product.

The parties will negotiate the terms of a definitive Collaboration and License Agreement pursuant to the terms of the MOU, using commercially reasonable efforts to execute such definitive agreement within a specified period of time. The terms of the MOU will remain in effect until a definitive Collaboration and License Agreement is executed.

In addition, we and Sandoz AG may negotiate additional collaboration agreements with respect to other mutually selected products. Sandoz AG has the right to (i) select a certain number of these mutually selected products and (ii) negotiate expanded territories for certain products already part of the collaboration; for which, if we and Sandoz AG do not execute a definitive agreement within a specified time frame, we are permitted to enter into a transaction for such opportunity with a third party, provided that the terms which we give to that third party can be no less favorable, taken as a whole, than the terms we last offered to Sandoz AG. If we do not enter into a transaction with a third party in a specified time frame, then the negotiations between us and Sandoz AG with respect to such product will start again, with the corresponding rights and obligations if the parties do not execute a definitive agreement within the specified time frame.

IND for M118

On July 27, 2006, we submitted an Investigational New Drug Application, or IND, to the FDA to begin a Phase I human clinical study of M118, our novel anticoagulant drug designed by us to specifically treat acute coronary syndromes, or ACS.

Patent Infringement Litigation with Sanofi-Aventis

On August 8, 2006, we learned that Aventis Pharmaceuticals Inc. and Aventis Pharma S.A., collectively Sanofi-Aventis, the holder of the New Drug Application, or NDA, for Lovenox, initiated litigation against Sandoz relating to the paragraph IV certification contained in the amended ANDA filed by Sandoz seeking approval to market M-Enoxaparin in the United States.

Under our 2003 Sandoz Collaboration, Sandoz has agreed to indemnify us and our collaborators involved in the M-Enoxaparin program, for any losses resulting from, among other things, any litigation by third parties, including Sanofi-Aventis, claiming that the manufacture, use or sale of injectable enoxaparin infringes any patents listed in the FDA s Orange Book for Lovenox. In the event that patent litigation expenses exceed a specified amount, Sandoz is permitted to offset a portion of the excess against profit-sharing amounts, royalties and the commercial milestone payments set forth in the 2003 Sandoz Collaboration. To the extent that any losses result from a third party claim for which we are obligated to indemnify Sandoz, Sandoz will have no obligation to indemnify us.

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, $30.2 million of revenue from our inception through June 30, 2006. This revenue was derived entirely from our 2003 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 Sandoz collaboration and similar future collaborative or strategic relationships. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of research and development and other payments received under our collaborative or strategic relationships, and the amount and timing of payments we receive upon the sale of our products, to the extent any are successfully commercialized.

Research and Development

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

The following summarizes our primary research and development programs:

Development Programs

M-Enoxaparin

Our most advanced product candidate, M-Enoxaparin, is designed to be a generic version of Lovenox. Lovenox is a widely-prescribed LMWH used for the prevention and treatment of deep vein thrombosis, or DVT, and treatment of ACS. Under our 2003 Sandoz Collaboration we jointly develop, manufacture and commercialize M-Enoxaparin and Sandoz is responsible for funding substantially all of the M-Enoxaparin development, regulatory, legal and commercialization costs. The total cost of development and commercialization and the timing of M-Enoxaparin marketing are subject to uncertainties relating to the development, regulatory approval and legal processes. In accordance with our 2003 Sandoz Collaboration, an ANDA was submitted to the FDA for M-Enoxaparin on August 29, 2005, seeking approval to market M-Enoxaparin in the United States.

We anticipate that the FDA s review of the M-Enoxaparin ANDA will require, among other things, a review of our technology and characterization methodology, as well as our manufacturing data. In parallel, we, in collaboration with Sandoz, are focused on activities related to supporting the ANDA submission, and the FDA s review of the ANDA and preparing for the commercialization of M-Enoxaparin, if and when approved, including advancing manufacturing, supply chain, and sales and marketing objectives.

M118

M118 is a novel anticoagulant drug that we rationally designed with the goal of providing improved clinical properties to treat patients diagnosed with stable angina and ACS. We believe M118 has the potential to provide baseline anticoagulant therapy to treat stable angina and ACS patients who require a coronary intervention, as well as those ACS patients who are medically managed, or do not require intervention in order to treat their coronary attack. M118 is designed to be a reversible and monitorable anticoagulant that can be administered intravenously or subcutaneously and has a pharmacokinetic profile, similar to a LMWH. Thus, it can be utilized irrespective of a patient s specific treatment path.

On July 27, 2006, we filed our IND application with the FDA for the intravenous administration of M118 and anticipate advancing M118 into Phase I clinical trials after the FDA allows the IND to become effective. Because M118 has not yet entered clinical development, we are not currently able to estimate the cost to complete the research and development phase nor are we able to estimate the timing of commercialization of M118.

Other Complex Mixture Drugs

We are exploring the application of our technology to the development of generic versions of selected complex mixture drugs. Complex mixtures include synthetic, semi-synthetic and naturally derived products and are composed of molecules that, due to their diversity, are difficult to fully characterize. Heparins are one example of complex mixture drugs. Drugs which are complex mixtures can be approved and regulated under either the NDA or Biological Licensing Application, or BLA, regulatory paths at the FDA. We are seeking to apply our technology to complex mixture products irrespective of the regulatory path under which each product was approved.

For complex mixtures approved as NDAs, we are applying our characterization technology to develop technology-enabled generic products. We have two development-stage generic product candidates, M-Dalteparin, and our other complex mixture program which we anticipate including in the 2006 Sandoz Collaboration, M356. We are at various stages of refining the characterization data and/or performing the process development work for these product candidates. We continue to advance our efforts toward a goal of submitting ANDAs for these products to the FDA. The total cost of development and commercialization and the timing of bringing M-Dalteparin and M356 to market are subject to uncertainties relating to the development, regulatory approval and legal processes.

M-Dalteparin is targeted to be a technology enabled generic version of Fragmin®, a LMWH product. Fragmin is indicated for the prevention of DVT and selected indications in ACS. In September 2005, Eisai Inc., a U.S. pharmaceutical subsidiary of Eisai Co. Ltd., obtained U.S. promotion rights to Fragmin from Pfizer Inc. Fragmin is marketed by Pfizer in Europe and by Kissei Pharmaceutical Co, Ltd. In Japan. Through our technology, we believe we have the ability to analyze Fragmin and demonstrate that M-Dalteparin has the same active ingredients as Fragmin, thereby enabling the FDA to approve an ANDA for Dalteparin. The Orange Book patent listed for Fragmin expired in January 2005.

For complex mixtures approved as BLAs, such as glycoprotein drugs, we are applying our technology to characterize and better understand these molecules. Product applications include: working with innovator biotechnology companies to help them better understand the sugars contained in their products; applying our technology to create technology-enabled follow-on products; and creating improved versions of glycoprotein products.

Discovery Programs

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

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

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, legal, accounting, investor relations, business development and human resource

functions. Other costs include facility and insurance costs not otherwise included in research and development expenses and professional fees for legal and accounting services.

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

Results of Operations

Three Months Ended June 30, 2006 and 2005

Revenue

Revenues for the three months ended June 30, 2006 and 2005 were $5.4 million and $3.4 million, respectively, which were entirely attributable to our 2003 Sandoz Collaboration.

Research and Development

The following table summarizes the primary components of our research and development expense for our principal research and development programs for the three months ended June 30, 2006 and 2005:

Research and Development Program (in thousands)	2006	2005
Development Programs	$ 10,816	$ 3,446
Discovery Programs	1,313	718
Other Research	1,342	835
Total research and development expense	$ 13,471	$ 4,999

Research and development expense for the three months ended June 30, 2006 was $13.5 million compared to $5.0 million during the three months ended June 30, 2005. The increase of $8.5 million from 2005 to 2006 principally resulted from an increase of $2.8 million in manufacturing costs and research conducted by third parties, $1.9 million in lab expenses, $1.2 million in stock-based compensation, of which $0.8 million is related to the adoption of SFAS 123R, $1.2 million in personnel and related costs, $0.9 million in facilities costs and $0.2 million in consultant costs.

Our drug development program increase of $7.4 million was primarily related to preclinical and toxicology work intended to support the M118 IND filing, manufacturing and professional fees related to our M-Enoxaparin program and the expenses of our M356 program. Our discovery program increase of $0.6 million was primarily related to expenditures supporting our drug delivery and disease biology programs.

General and Administrative

General and administrative expense for the three months ended June 30, 2006 was $6.1 million compared to $3.2 million during the three months ended June 30, 2005. The increase of $2.9 million was primarily due to an increase of $1.2 million in stock-based compensation, of which $0.6 million is related to the adoption of SFAS 123R, $1.0 million in personnel and related costs and $0.6 million in professional fees.

Interest Income and Expense

Interest income increased to approximately $1.7 million for the three months ended June 30, 2006 from approximately $0.3 million for the three months ended June 30, 2005, primarily due to higher average investment balances in 2006 substantially as a result of the proceeds from our follow-on public offering in July 2005. Interest expense increased from approximately $34,000 during the three months ended June 30, 2005 to approximately $0.1 million for the three months ended June 30, 2006 due to additional amounts drawn from our equipment line of credit during 2005 and 2006.

Six Months Ended June 30, 2006 and 2005

Revenue

Revenues for the six months ended June 30, 2006 and 2005, which were entirely attributable to our 2003 Sandoz Collaboration, were $7.9 million and $6.8 million, respectively. These revenues consist of amounts earned by us for reimbursement by Sandoz of research and development services and reimbursement of development costs for M-Enoxaparin and amortization of the initial payment received under our 2003 Sandoz Collaboration.

Research and Development

The following table summarizes the primary components of our research and development expense for the six months ended June 30, 2006 and 2005:

Research and Development (in thousands)	2006	2005
Development programs	$ 17,991	$ 6,983
Discovery programs	2,586	1,326
Other research	2,339	1,621
Total research and development expense	$ 22,916	$ 9,930

Research and development expense for the six months ended June 30, 2006 was $22.9 million compared to $9.9 million during the six months ended June 30, 2005. The increase of $13.0 million from 2005 to 2006 principally resulted from an increase of $3.8 million in manufacturing costs and research conducted by third parties, $2.7 million in lab expenses, $2.1 million in personnel and related costs, $1.9 million in stock-based compensation, of which $1.3 million is related to the adoption of SFAS 123R, $1.7 million in facilities costs and $0.4 million in consultant costs.

Our drug development program increase of $11.0 million was primarily related to preclinical and toxicology work intended to support the M118 IND filing, manufacturing and professional fees related to our M-Enoxaparin Program and the expenses of our M356 program. Our discovery program increase of $1.3 million was primarily related to expenditures supporting our drug delivery and disease biology programs.

General and Administrative

General and administrative expenses for the six months ended June 30, 2006 was $12.1 million compared to $5.8 million during the six months ended June 30, 2006. The increase of $6.3 was primarily due to an increase of $2.5 in stock-based compensation, of which $1.7 million is related to the adoption of SFAS 123R, $2.1 million in personnel and related costs and $1.3 in professional fees.

Interest Income and Expense

Interest income increased to approximately $3.3 million for the six months ended June 30, 2006 from approximately $0.6 million for the six months ended June 30, 2005, primarily due to higher average investment balances in 2006 substantially as a result of the proceeds from our follow-on public offering in July 2005. Interest expense increased from approximately $0.1 million during the six months ended June 30, 2005 to approximately $0.2 million for the six months ended June 30, 2006 due to additional amounts drawn from our equipment line of credit during 2005 and 2006.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of equity securities, payments from our 2003 Sandoz Collaboration, borrowings from our lines of credit, and capital lease obligations. Since our inception, we have received net proceeds of $45.4 million from the issuance of redeemable convertible preferred stock. In June 2004, we completed our initial public offering and raised

net proceeds of $35.3 million. In July 2005, we completed a follow-on public offering and raised net proceeds of $122.3 million. As of June 30, 2006, we have received $26.9 million from our 2003 Sandoz Collaboration, $4.0 million from debt financing, $3.2 million from capital lease obligations, $1.2 million from our landlord for leasehold improvements related to our corporate facility and additional funds from interest income. In July 2006, we entered into the 2006 Sandoz Collaboration, which, subject to closing and HSR clearance, would result in our receiving net proceeds of $75 million from Novartis Pharma AG, in connection with the sale of 4,708,679 shares of our common stock.

At June 30, 2006, we had $139.9 million in cash, cash equivalents and marketable securities. In addition, we also hold $1.8 million in restricted cash which serves as collateral for a letter of credit related to our facility lease. Net cash used in operating activities for the six months ended June 30, 2006 and 2005 was $13.6 million and $5.6 million, respectively. The use of cash in each period was primarily a result of net losses associated with our research and development activities and administrative costs.

Net cash provided by investing activities for the six months ended June 30, 2006 and 2005 was $25.9 million and $0.6 million, respectively. In the first six months of 2006, we used $47.7 million of cash to purchase marketable securities and had $78.7 million in maturities of marketable securities. In the first six months of 2005, we used $27.6 million of cash to purchase marketable securities and had $29.9 million in maturities of marketable securities. In the first six months of 2006 and 2005, we used $5.0 million and $1.7 million, respectively, to purchase equipment and leasehold improvements.

Net cash provided by financing activities for the six months ended June 30, 2006 was $2.5 million. We had borrowings of $1.3 million on an equipment lease agreement entered into in December 2005, received $1.2 million in financing from our landlord for leasehold improvements related to our corporate facility, and received proceeds of $0.4 million from stock option exercises and purchases of common shares through our Employee Stock Purchase Plan, offset by principal payments of $0.4 million on our line of credit and lease agreement obligations. Net cash provided by financing activities for the six months ended June 30, 2005 was $1.1 million. We had net borrowings of $1.0 million on our line of credit obligation, and received proceeds of $0.1 million from stock option exercises, purchases of common shares through our Employee Stock Purchase Plan and a payment related to restricted stock.

In June 2006, the construction of leasehold improvements in our corporate facility was completed. In July 2006, the Company signed a non-binding letter of intent to sublease approximately 22,700 square feet of additional laboratory and office space, with a term through April 2011. As of June 30, 2006, the Company had borrowed $3.2 million under an equipment lease agreement, which is equal to the total authorized commitment.

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, 2005 have not materially changed since we filed that report.

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

Funding Requirements

We have received $26.9 million as of June 30, 2006 from our 2003 Sandoz Collaboration. Under our 2003 Sandoz Collaboration, Sandoz has agreed to fund a minimum amount of personnel and substantially all of the other ongoing development, commercialization and legal expenses incurred with respect to our M-Enoxaparin program, subject to the right to terminate if certain costs exceed mutually agreed upon limits.

We expect to use our current cash, cash equivalents and marketable securities to continue the development of our product candidates, our discovery research programs and for other general corporate purposes. We intend to use the majority of our cash to fund: our development programs, including M-

Enoxaparin, M118, M-Dalteparin, M356, and the application of our technology to other complex drugs including glycoproteins and complex mixtures. Also, we will use funds to advance our discovery programs, which are focused on identifying novel therapeutics and technologies; the potential acquisition of companies, products and technologies that complement our business; and working capital, capital expenditures and other general corporate purposes.

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

the advancement of our generic product candidates and other development programs;

the timing, receipt and amount of milestone and other payments, if any, from present and future collaborators;

the time and costs involved in obtaining regulatory approvals;

the continued progress in our research and development programs, including completion of our preclinical studies and clinical trials;

the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims;

the potential acquisition and in-licensing of other technologies, products or assets;

the timing, receipt and amount of sales and royalties, if any, from our product candidates;

the cost of manufacturing, marketing and sales activities, if any; and

the cost of litigation, including potential patent litigation.

We do not expect to generate significant additional revenues, other than payments that we receive from our 2003 Sandoz Collaboration or other similar future collaborations, until we successfully obtain marketing approval for, and begin selling, M-Enoxaparin. We believe the key factors that will affect our internal and external sources of cash are:

our ability to successfully develop, manufacture, obtain regulatory approval for and commercialize M-Enoxaparin;

the success of our development programs, including our generic product candidates and programs involving preclinical and clinical development;

the receptivity of the capital markets to financings by biotechnology companies;

the success of our current strategic collaborations; and

our ability to enter into additional strategic collaborations with corporate and academic collaborators and the success of such collaborations.

If our existing resources, including the proceeds of our initial public offering and July 2005 follow-on offering are insufficient to satisfy our liquidity requirements, if the 2006 Sandoz Collaboration does not close or if we acquire or license additional technologies, products or assets that fit within our growth strategy, we may need to raise additional external funds through the sale of equity or debt securities. The sale of equity securities may result in dilution to our stockholders. Additional financing may not be available in amounts or on terms acceptable to us or at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned

research, development and commercialization activities, which could harm our financial condition and operating results.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an on-going basis, we evaluate our estimates and judgments,

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

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

Revenue

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

Accrued Expenses

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

Stock-Based Compensation

Effective January 1, 2006, we adopted the fair value recognition provisions of Financial Accounting Standards Board s Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, or SFAS 123R, using the modified prospective transition method. Total compensation cost for all share-based payment arrangements for the three months ended June 30, 2006 and 2005 was $3.0 million and $0.6 million, respectively. Total compensation cost for all share-based payment arrangements for the six months ended June 30, 2006 and 2005, was $5.4 million and $1.0 million, respectively. At June 30, 2006, the total unrecognized compensation cost related to nonvested stock options was $12.0 million. We expect to recognize this cost over a weighted average period of 2.5 years.

Prior to January 1, 2006, we accounted for employee stock options under the recognition and measurement provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and provided pro forma disclosures of net loss attributable and net loss per share allocable to common stockholders as if we had adopted the fair value based method of accounting in accordance with SFAS No. 123, or SFAS 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, or SFAS 148, *Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123*.

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, 2006, 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, 2006. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2006, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Statements contained or incorporated by reference in this Quarterly Report on Form 10-Q that are not based on historical fact are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, and projections and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, general and administrative expenses, research and development expenses, development and manufacturing efforts, regulatory filings and the sufficiency of our cash for future operations. Forward-looking statements may be identified by the use of forward-looking terminology such as believe , may, could, will, expect, estimate, anticipate, continue, or similar terms, variations of such terms or the negative of those terms.

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

The following discussion includes seven revised risk factors (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, we may have to curtail our development programs and our business would be materially harmed. ; If other generic versions of Lovenox are approved and successfully commercialized our business would suffer ; If the FDA is not able to establish specific guidelines or arrive at a consensus regarding the scientific analyses required for characterizing complex protein drugs, and if the U.S. Congress does not take action to create an abbreviated regulatory pathway for follow-on protein products, then the uncertainty about the value of our glycoprotein program will be increased ; If our preclinical studies and clinical trials for our development candidates, including M-118, are not successful, we will not be able to obtain regulatory approval for commercial sale of our novel or improved drug candidates ; New federal legislation will increase the pressure to reduce prices of pharmaceutical products paid for by Medicare, which could adversely affect our revenues, if any ; 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; and Our stock price may be volatile, and purchasers of our common stock could incur substantial losses), that reflect developments subsequent to the discussion of risk factors included in our most recent Annual Report on Form 10-K. In addition, the risk factor entitled Changes in stock option accounting rules may have a significant adverse affect on our operating results was deleted.

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, 2006, our accumulated deficit was approximately $97.5 million. We have not generated revenues from the sale of any products to date. We expect that our annual operating losses will increase over the next several years as we expand our drug commercialization, development and discovery efforts. To become profitable, we must successfully develop, and obtain regulatory approval for, our existing drug candidates, and effectively manufacture, market and sell any drugs we develop. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve profitability.

To become and remain profitable, we must succeed in developing and commercializing drugs with significant market potential. This will require us to be successful in a range of challenging activities: developing drugs; obtaining regulatory approval for them; and manufacturing, marketing and selling them. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would

cause the market price of our common stock to decrease and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

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

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

In accordance with our 2003 Sandoz Collaboration, an ANDA was submitted to the FDA on August 29, 2005, seeking approval to market M-Enoxaparin in the United States. FDA approval of an ANDA is required before marketing of a generic equivalent of a drug previously approved under an NDA. 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 our ANDA, including but not limited to manufacturing and bioequivalence requirements, or obtain FDA approval for, and successfully commercialize, M-Enoxaparin, we may never realize revenue from this product and we may have to curtail our other product development programs. As a result, our business would be materially harmed.

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, we may have to curtail our development programs and our business would be materially harmed.

On August 8, 2006 we learned that in response to Sandoz paragraph IV certification contained in the amended ANDA filed by Sandoz seeking approval to market M-Enoxaparin in the United States, Sanofi-Aventis, filed a patent infringement lawsuit against Sandoz Inc. in the United States District Court for the District of New Jersey.

Companies that produce branded pharmaceutical products for which there are unexpired patents listed in the FDA s 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 FDA s listing of approved drug products, the FDA s Orange Book Orange Book. These patents are U.S. Patent No. 5,389,618 or the 618 Patent, and its counter-part, Reissue Patent No. 38,743, or the 743 Reissue Patent. On June 14, 2005, the 743 Reissue Patent issued and the original 618 Patent was surrendered by operation of law. 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 ceases to exist and has been replaced by the 743 Reissue Patent. According to the Orange Book, the 743 Reissue Patent expires February 14, 2012.

In June 2003, prior to issuance of the 743 Reissue Patent, Sanofi-Aventis announced that it received individual notices from Amphastar Pharmaceuticals, Inc., or Amphastar, and Teva Pharmaceuticals USA, Inc., or Teva, indicating that each had submitted with the FDA its own ANDA for enoxaparin. According to Sanofi-Aventis, each ANDA included a paragraph IV certification, or a patent certification, stating that the 618 Patent was either not infringed, unenforceable or invalid. Amphastar and Teva submitted this patent certification because they were seeking from the FDA authorization to manufacture and market a generic version of Lovenox in the United States prior to the expiration of the 618 Patent. Submitting such certifications allowed Sanofi-Aventis to sue Amphastar and Teva for patent infringement of the 618 Patent, even though Amphastar and Teva have neither obtained approval for nor marketed their generic versions of Lovenox in the United States.

In response to Sanofi-Aventis lawsuit, Amphastar and Teva asserted non-infringement, invalidity and/or unenforceability of the 618 Patent and sought related declaratory judgment relief against Sanofi-Aventis, as well as counterclaims for antitrust violations, common law unfair business practices, unjust enrichment and statutory unfair business practices. The Amphastar and Teva lawsuits were consolidated and brought before the U.S. District Court for the Central District of California, or District Court.

In June 2005, Amphastar and Teva each subsequently amended their own ANDA to include a second paragraph IV certification for the 743 Reissue Patent. The 743 Reissue Patent was then substituted in the pending action for the 618 patent.

On June 16, 2005, the District Court granted summary judgment to Amphastar finding that the 743 Reissue Patent was unenforceable due to Aventis inequitable conduct before the United

If we fail to obtain approval for and commercialize our most advanced product candidate, M-Enoxaparin, we may ha

States Patent and Trademark Office, or USPTO. Accordingly, in August 2005, the District Court entered final judgment in favor of Teva and Amphastar on their counterclaims of unenforceability. Thereafter, Sanofi-Aventis filed an appeal of the District Court s decision and final judgment of unenforceability based on inequitable conduct to the U.S. Court of Appeals for the Federal Circuit, or Court of Appeals.

On April 10, 2006, the Court of Appeals determined that although there were no genuine issues of material fact with respect to the materiality of certain dosage information withheld from the USPTO, there remained genuine issues of material fact that such omission was made with intent to deceive the USPTO. Accordingly, the Court of Appeals reversed the District Court s granting of summary judgment of inequitable conduct and remanded the case to the District Court for further proceedings consistent with the Court of Appeals decision.

On or about July 28, 2006 the District Court indicated that it will conduct a bench trial focused only on inequitable conduct, consistent with the Court of Appeals Decision. A final schedule as to the date of the trial on inequitable conduct has not yet been set. The District Court also indicated that, within a short period upon conclusion and decision of the District Court on inequitable conduct, all other remaining issues will be tried by the District Court. A final decision by the District Court on the issue of inequitable conduct could be appealed resulting in further delays.

The Sandoz, Teva or Amphastar proceedings could delay or prevent the introduction of M-Enoxaparin until expiry of the 743 Reissue Patent if, for example, the 743 Reissue Patent is found valid and enforceable. In addition, Sanofi-Aventis could settle the lawsuit with both Teva and Amphastar at any point prior to a final District Court decision and consequently the 743 Reissue patent would remain as a barrier to the marketing of other generic versions of enoxaparin, until this patent has expired or is otherwise held invalid, unenforceable or non-infringed by a District Court.

Under our 2003 Sandoz Collaboration, in most circumstances, the decision as to when to begin marketing M-Enoxaparin will be determined jointly by us and Sandoz. Sandoz, however, has sole discretion over the decision as to when to begin marketing M-Enoxaparin under certain circumstances. Sandoz has agreed to indemnify us for patent liability damages, subject to Sandoz s ability to offset certain of these liabilities against the profit-sharing amounts, the royalties and the milestone payments otherwise due to us from the marketing of M-Enoxaparin.

Intellectual property litigation involves many risks and uncertainties, and there is no assurance that Amphastar, Teva, Sandoz or we will prevail in any lawsuit with Sanofi-Aventis. In addition, Sanofi-Aventis has significant resources and litigation with Sanofi-Aventis could last a number of years, potentially delaying or prohibiting the commercialization of M-Enoxaparin. If we are not successful in commercializing M-Enoxaparin or are significantly delayed in doing so, we may have to curtail our product development programs and our business would be materially harmed.

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

Some of our products in current or future development, including M-Enoxaparin, may be based on new technologies that have not previously been formally reviewed or accepted by the FDA or other

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

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

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

If we experience manufacturing difficulties or are unable to obtain sufficient quantities of raw materials or manufacture sufficient quantities of M-Enoxaparin, our development and commercialization efforts may be materially harmed.

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon third parties to provide raw materials, to manufacture the drug substance, or active pharmaceutical ingredient, for M-Enoxaparin and to provide certain other services relating to M-Enoxaparin. We also depend on additional third parties to produce the final drug product and provide certain analytical services with respect to M-Enoxaparin. Manufacturing requirements, including but not limited to, reproducibility, validation and scale-up, must be addressed in order to satisfy FDA requirements necessary for approval and commercialization of M-Enoxaparin. In addition, if the product is approved, in order to produce M-Enoxaparin in the quantities necessary to meet anticipated market demand, we and any contract manufacturer that we engage may need to increase manufacturing capacity. If we are unable to satisfy the FDA requirements for approval or to produce M-Enoxaparin in sufficient quantities to meet the requirements for the launch of the product or to meet future demand, our revenues and gross margins could be adversely affected.

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

In addition to general competition in the pharmaceutical market, we expect that certain of our generic product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. Revenues and gross profit derived from the sales of generic pharmaceutical products tend to follow a pattern based on certain regulatory and competitive factors. As patents for

branded products and related exclusivity periods expire, manufacturers of generic products may receive regulatory approval for generic equivalents and may be able to achieve significant market penetration. As competing off-patent manufacturers receive regulatory approvals on similar products or as branded manufacturers launch authorized generic versions of such products, market share, revenues and gross profit typically decline, in some cases, dramatically. If any of our generic product offerings, including M-Enoxaparin, enter markets with a number of competitors, we may not achieve significant market share, revenues or gross profit. In addition, as other generic products are introduced to the markets in which we participate, the market share, revenues and gross profit of our generic products could decline.

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

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

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

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

Many of our competitors have:

significantly greater financial, technical and human resources than we have at every stage of the discovery, development, manufacturing and commercialization process;

more extensive experience in commercializing generic drugs, preclinical testing, conducting clinical trials, obtaining regulatory approvals, challenging patents and in manufacturing and marketing pharmaceutical products;

products that have been approved or are in late stages of development; and

collaborative arrangements in our target markets with leading companies and research institutions.

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

the safety and effectiveness of our products;

the timing and scope of regulatory approvals for these products;

the availability and cost of manufacturing, marketing and sales capabilities;

the effectiveness of our marketing and sales capabilities;

the price of our products;

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

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.

Competition in the biotechnology and pharmaceutical industries is intense, and if we are unable to compete effectiv

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

Generic pharmaceutical products are sold through various channels, including retail and mail order, and to hospitals through group purchasing organizations, or GPOs. As M-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, and 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. If we are unable to establish and maintain arrangements with all of these customers, future sales of our products, revenues and profits would suffer.

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

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

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

the timing of our receipt of any marketing approvals, the terms of any approval and the countries in which approvals are obtained;

the safety, efficacy and ease of administration of our products;

the competitive pricing of our products;

the success of our physician education and marketing programs;

the sales and marketing efforts of competitors; and

the availability and amount of government and third-party payor reimbursement.

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

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

As of June 30, 2006, we had cash, cash equivalents and marketable securities totaling $139.9 million. For the six months ended June 30, 2006, we had a net loss of $23.9 million and used cash in operating activities of $13.6 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.

We will require substantial additional funds to execute our business plan and, if additional capital is not available, w

Our future capital requirements may vary depending on the following:

the advancement of our generic product candidates and other development programs;

the cost of litigation, including potential patent litigation with Sanofi-Aventis relating to Lovenox that is not otherwise covered by our collaboration agreement, or potential patent litigation with others, as well as any damages,

including possibly treble damages, that may be owed to Sanofi-Aventis or others should we be unsuccessful in such litigation;

the time and costs involved in obtaining regulatory approvals;

the continued progress in our research and development programs, including completion of our preclinical studies and clinical trials;

the potential acquisition and in-licensing of other technologies, products or assets; and

the cost of manufacturing, marketing and sales activities, if any.

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

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

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

There is a substantial risk of product liability claims in our business. If our existing product liability insurance is insufficient, a product liability claim against us that exceeds the amount of our insurance coverage could adversely affect our business.

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

There is a substantial risk of product liability claims in our business. If our existing product liability insurance is insuf

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

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

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

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

we may find that the acquired company or assets do not further our business strategy, or that we overpaid for the company or assets, or that economic conditions change, all of which may generate a future impairment charge;

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

we may have difficulty incorporating the acquired technologies;

we may encounter technical difficulties or failures with the performance of the acquired technologies or drug products;

we may face product liability risks associated with the sale of the acquired company s products;

our ongoing business and management s attention may be disrupted or diverted by transition or integration issues and the complexity of managing diverse locations;

we may have difficulty maintaining uniform standards, internal controls, procedures and policies across locations;

the acquisition may result in litigation from terminated employees or third-parties; and

we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

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

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

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

Risks Relating to Development and Regulatory Approval

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

Our future results of operations depend, to a significant degree, on our ability to obtain regulatory approval for and commercialize generic versions of complex drugs, including M-Enoxaparin. We will be required to demonstrate to the satisfaction of the FDA, among other things, that our generic products contain the same active ingredients, are of the same dosage form, strength and route of administration as the branded products upon which they are based, and meet compendial or other applicable standards for strength, quality, purity and identity, including potency. Our generic versions of complex drugs, including M-Enoxaparin and potentially others, must also be demonstrated through *in vivo* studies to be bioequivalent, meaning generally that there are no significant differences between the generic drug and its branded counterpart with respect to the rate and extent to which the active ingredients are absorbed and become available at the site of drug action.

Determination of the same active ingredients for our generic versions of complex drugs will be based on our demonstration of chemical equivalence to the respective reference listed drugs. The FDA may not agree that we have adequately characterized our products or that our products are equivalent to their respective branded drugs. The FDA may require confirmatory information including, for example, animal or human testing, to determine the sameness of active ingredients and that any inactive ingredients or impurities do not compromise the product s safety and efficacy. Provision of sufficient information for approval may prove difficult, time consuming and expensive. We must also demonstrate the adequacy of our methods, controls and facilities used in the manufacture of the product, including that they meet current good manufacturing practices, or cGMP. We cannot predict whether any of our generic product candidates will meet FDA requirements for approval.

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

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

The regulatory climate for generic or follow-on versions of protein products remains very uncertain. Currently, there is no established statutory or regulatory pathway which provides the FDA with the authority to approve follow-on versions of most protein drugs. The FDA has approved the majority of protein products under the Public Health Service Act through the use of Biologics License Applications, or BLAs. Unlike products approved through the submission of new drug applications or NDAs under section 505 of the Federal Food, Drug, and Cosmetic Act, there is no provision in the Public Health Service Act for an abbreviated BLA that would permit approval of a follow-on protein product, and the FDA has stated it does not believe it has the authority to rely on prior BLA approvals or on their underlying data to approve a follow-on product. Moreover, even for proteins originally approved as NDAs, there is debate as to the data necessary to demonstrate the sameness required for ANDA approval under section 505(j) as well as opposition to the FDA s use of section 505(b)(2) to approve follow-on versions of protein and other complex drug products approved under section 505. On May 30, 2006, the FDA approved Sandoz s recombinant human growth hormone Omnitrope under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. The FDA interprets section 505(b)(2) to allow an applicant to rely on published data and/or a finding of safety and effectiveness for a pioneer NDA for approval. With regard to Omnitrope, the FDA stated that human growth hormone is well characterized and understood and Omnitrope was sufficiently similar to the pioneer NDA drug Genotropin to allow Sandoz to rely on the FDA s finding of safety and effectiveness for Genotropin to support approval of Omnitrope under section 505(b)(2); Sandoz also submitted preclinical and clinical data generated by Sandoz to support approval. The FDA further stated that the approval of Omnitrope as a follow-on protein did not provide an abbreviated pathway for follow-on products to products licensed under the Public Health Service Act and did not guarantee follow-on approval for more complex and/or less understood drugs under section 505(b)(2), even if such drugs were originally submitted as NDAs.

Although the FDA has stated its intentions to draft guidances applicable to follow-on protein products, the agency has not stated a timeline for action and to our knowledge, no guidance documents or other publications have been provided by the FDA to date regarding an abbreviated approval pathway for follow-on products to licensed biologics. Failure of the FDA to establish standards or the U.S. Congress to enact legislation establishing such a pathway for regulatory approval could reduce the value of our glycoprotein program.

If the FDA is not able to establish specific guidelines or arrive at a consensus regarding the scientific analyses requ

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 will be required to demonstrate through preclinical studies and clinical trials that our drug development candidates are safe and effective. Preclinical testing and clinical trials of new development candidates are lengthy and expensive and the historical failure rate for development candidates is high. The results from preclinical testing of a development candidate may not predict the results that will be obtained in human clinical trials. Clinical trials including clinical trials for M118, cannot commence until an IND is submitted containing sufficient preclinical data and other information to support use in human subjects and the FDA allows the trials to go forward. Clinical trials must also be reviewed and approved by institutional review boards, or IRBs, for each clinical trial site before a development candidate may be used in a human trial at that site. We, the FDA or other applicable regulatory authorities or an IRB may prohibit the initiation of, or suspend clinical trials of, a development candidate, including M118, at any time if we or they believe the subjects or patients participating in such trials are being exposed to unacceptable health risks, or for other reasons. Adverse side effects of a development candidate on subjects or patients in a clinical trial could result in the FDA or other regulatory authorities refusing to approve a particular development candidate, including M118, for any or all indications of use.

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

We cannot predict whether any of our development candidates, including M118, will encounter problems during clinical trials which will cause us or regulatory authorities to delay or suspend these trials, or which will delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate, including M118, that is affected or the development of any of our other drug candidates.

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

Although we have not initiated any marketing efforts in foreign jurisdictions, we intend in the future to market our products outside the United States. In order to market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval abroad may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with

obtaining FDA approval, and we may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States. The failure to obtain these approvals could materially adversely affect our business, financial condition and results of operations.

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

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

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

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

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

either experimental nor investigational.

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

Medicaid or other data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

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

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

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

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

Congress has considered separate legislation, which if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States and which may include re-importation from foreign countries where drugs are frequently sold at lower prices than in the United States; other proposed legislation would remove restrictions on CMS ability to negotiate discounts directly with prescription drug manufacturers provided through the Medicare program. Such legislation, or similar regulatory changes, could decrease the amount of reimbursement we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition.

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

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

innovator companies settling patent lawsuits with generic companies, resulting in such patents not being held invalid or unenforceable, and as a result, such patents remaining an obstacle for generic approval by others;

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

submitting Citizen Petitions to request the Commissioner of Food and Drugs 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 may issue before the expiration of one patent, which could extend patent protection for a number of years or otherwise delay the launch of generic drugs;

attaching special patent extension amendments to unrelated federal legislation.

Further, some manufacturers of branded products have engaged in state-by-state initiatives to enact legislation that restrict the substitution of some branded drugs with generic drugs. If these efforts to delay or block competition are successful, we may be unable to sell our generic products, which could have a material adverse effect on our sales and profitability.

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

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

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

Our research and development involves, and may in the future involve, the use of hazardous materials and chemicals and certain radioactive materials and related equipment. For the years ended December 31, 2005, 2004, and 2003, we spent approximately $19,000, $25,000, and $17,500, respectively, in order to comply with environmental and waste disposal regulations. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Although we maintain workers compensation insurance as prescribed by the Commonwealth of Massachusetts to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. For claims not covered by workers compensation insurance, we also maintain an employer s liability insurance policy in the amount of $3.5 million per occurrence and in the aggregate. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Risks Relating to Our Dependence on Third Parties

Our 2003 Sandoz Collaboration is important to our business. If Sandoz fails to adequately perform under our collaboration or terminates our collaboration, the development and commercialization of injectable enoxaparin would be delayed or terminated and our business would be adversely affected.

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

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

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

We depend on third-parties for the manufacture of products. If in the future we encounter difficulties in our supply or manufacturing arrangements, our business may be materially adversely affected.

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. In addition, we do not have, and do not intend to develop, the ability to manufacture material for our clinical trials or at commercial scale. To develop our drug candidates, apply for regulatory approvals and commercialize any products, we or our partners need to contract for or otherwise arrange for the necessary manufacturing facilities and capabilities. As a result, we expect generally to rely on contract manufacturers for regulatory compliance. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected products or drug candidates could be delayed, which could have a material adverse effect on our business. In addition, any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

We have relied upon third parties to produce material for preclinical studies and may continue to do so in the future. Although we believe that we will not have any material supply issues, we cannot be certain that we will be able to obtain long-term supply arrangements of those materials on acceptable

terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

In addition, the FDA and other regulatory authorities require that our products be manufactured according to cGMP regulations. Any failure by us or our third-party manufacturers to comply with cGMP, and/or our failure to scale-up our manufacturing processes could lead to a delay in, or failure to obtain, regulatory approval. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action. To the extent we rely on a third-party manufacturer, the risk of non-compliance with cGMPs may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed.

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

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

In addition to relying on a third party for its capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our drug candidates. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular drug candidate internally, or to bring drug candidates to market. Failure to bring our drug candidates to market will prevent us from generating sales revenues, and this may substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market. As a result, our business may be adversely affected.

We enter into collaboration agreements and other similar contracts with other companies to supplement and enhance our own capabilities. If we are unable to enter into such agreements with companies or if any collaborative partner terminates or fails to perform its obligations under agreements with us, the development and commercialization of our drug candidates could be delayed or terminated.

Our continued and expected dependence on collaborative partners for their drug development, manufacturing, sales, marketing and distribution capabilities, for their financial support and/or to supplement and enhance our own proprietary technology platform, means that our business would be adversely affected if a partner terminates its collaboration agreement with us or fails to perform its obligations under the agreement. Our current collaborations and future collaborations, if any, may not be scientifically or commercially successful. Factors that may affect the success of our collaborations include the following:

- disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;

our collaborators may pursue alternative technologies or develop alternative products, either on their own or in collaboration with others, that may be competitive with the products on which they are collaborating with us or which could affect our collaborators commitment to our collaborations;

our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect how we are perceived in the business and financial communities;

our collaborators may pursue higher-priority programs or change the focus of their development programs, which could affect the collaborators commitment to us; and

our collaborators with marketing rights may choose to devote fewer resources to the marketing of our product candidates, if any are approved for marketing, than to products from their own development programs.

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

We enter into technology collaboration agreements and other similar contracts with other companies to supplement and enhance our own proprietary technology platform. If we are unsuccessful in forming or maintaining these collaborations on favorable terms or if the arrangements do not yield the intended results, our business could be adversely affected.

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. This may result in delays and our business may be adversely affected.

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

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

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

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

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

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

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

Risks Relating to Patents and Licenses

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

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

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

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex

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

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

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

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

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

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

We may need to resort to litigation to enforce a patent issued to us or to determine the scope and validity of third-party proprietary rights. The cost to us of any litigation or other proceeding relating to

intellectual property rights, even if resolved in our favor, could be substantial, and the litigation could divert our management s efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

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

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

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

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers, advisors and others. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

General Company Related Risks

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

Our directors, executive officers and principal stockholders, together with their affiliates and related persons, beneficially owned, in the aggregate, approximately 42% of our outstanding common stock as of June 30, 2006. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

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

entrenching our management and/or board;

impeding a merger, consolidation, takeover or other business combination involving our company; r

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

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

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

a classified board of directors;

a prohibition on actions by our stockholders by written consent;

a poison pill in accordance with the Company s Shareholders Rights Plan that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

limitations on the removal of directors.

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

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

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

failure to obtain FDA approval for M-Enoxaparin or other adverse FDA decisions relating to M-Enoxaparin including the FDA requiring clinical trials as a condition of M-Enoxaparin approval or the FDA s approval of other companies ANDAs;

litigation involving our company or our general industry or both, including potential litigation or a settlement with Sanofi-Aventis relating to M-Enoxaparin;

failure to obtain HSR or other applicable clearance for the 2006 Sandoz Collaboration;

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 and safety and efficacy for our novel development product candidates;

our ability to manufacture any products to commercial standards;

failure of any of our product candidates, if approved, to achieve commercial success;

Our directors, executive officers and major stockholders have substantial control over matters submitted to stockho

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.

Our stock price may be volatile, and purchasers of our common stock could incur substantial losses. 65

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

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

Use of Proceeds

On June 25, 2004, we sold 5,350,000 shares, together with an additional 802,500 shares pursuant to the exercise by the underwriters of an over-allotment option, of our common stock in connection with the closing of our initial public offering (the Offering). The Registration Statement on Form S-1 (Reg. No. 333-113522) we filed to register our common stock in the Offering was declared effective by the Securities and Exchange Commission on June 21, 2004.

From June 25, 2004 to June 30, 2006, we have expended approximately $17.7 million of the $35.3 million in net proceeds of the Offering. Such proceeds were primarily expended on our operating activities, including the research and development expenses, on our development programs including M118, M-Dalteparin and M356, and our discovery programs, including pulmonary delivery and novel therapeutics and technologies, as well as related general and administrative expenses. We utilized approximately $12.7 million to fund our operations, approximately $4.7 million to fund capital leasehold improvements and equipment purchases and approximately $0.3 million to make principal payments on our lease obligations and line of credit.

All of the remaining net proceeds of Offering have been invested into investment-grade marketable securities. None of the net proceeds were directly or indirectly paid to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

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

Our Annual Meeting of Stockholders was held on June 15, 2006.

There were present at the Annual Meeting in person or by proxy stockholders holding an aggregate of 23,121,099 shares of common stock. The results of the vote taken at the Annual Meeting with respect to the election of the nominees to be Class II Directors were as follows:

Class II Director Nominees	For	Withheld
John K. Clarke	20,199,273	2,921,826
Robert S. Langer, Jr.	16,091,253	7,029,846
Stephen T. Reeders	20,199,773	2,921,326

In addition, a vote of the stockholders was taken at the Annual Meeting with respect to the proposal to ratify the selection by the Audit Committee of the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2006. For the purpose of such vote, 23,094,922 shares voted in favor of such proposal, 2,049 shares were voted against such proposal and 24,127 shares abstained from voting.

Item 6. Exhibits.

10.1 Side letter dated June 29, 2006 between Vertex Pharmaceuticals Incorporated and Momenta Pharmaceuticals, Inc.

31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1 Certification Pursuant to 18 U.S.C. Section 1350.

SIGNATURES

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

Momenta Pharmaceuticals, Inc.

Date: August 9, 2006

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

Date: August 9, 2006

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