Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(MARK ONE)

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

For the quarterly period ended September 30, 2012

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

For the Transition Period from to

Commission File Number 000-50797

Momenta Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Its Charter)

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

(617) 491-9700
(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

Indicate the number of shares outstanding of each of the Registrant's classes of Common Stock as of November 2, 2012.

Class	**Number of Shares**
Common Stock $0.0001 par value	51,694,776

MOMENTA PHARMACEUTICALS, INC.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2012	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 84,897	$ 49,245
Marketable securities	276,921	299,193
Accounts receivable	4,951	28,171
Unbilled revenue	1,184	2,765
Prepaid expenses and other current assets	3,953	2,547
Restricted cash	—	17,500
Total current assets	371,906	399,421
Property and equipment, net	23,346	13,327
Restricted cash	19,971	—
Intangible assets, net	6,976	7,772
Other long-term assets	400	389
Total assets	$ 422,599	$ 420,909
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,721	$ 4,709
Accrued expenses	7,949	9,131
Deferred revenue	5,324	2,156
Deferred rent	200	32
Total current liabilities	20,194	16,028
Deferred revenue, net of current portion	27,631	1,608
Deferred rent, net of current portion	—	144
Other long-term liabilities	51	51
Total liabilities	47,876	17,831
Stockholders' Equity:		
Preferred stock, $0.01 par value per share; 5,000 shares authorized at September 30, 2012 and December 31, 2011, 100 shares of Series A Junior Participating Preferred Stock, $0.01 par value per share designated and no shares issued and outstanding	—	—
Common stock, $0.0001 par value per share; 100,000 shares authorized at September 30, 2012 and December 31, 2011, 51,702 and 51,285 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	5	5
Additional paid-in capital	518,921	506,557
Accumulated other comprehensive income (loss)	171	(81)
Accumulated deficit	(144,374)	(103,403)
Total stockholders' equity	374,723	403,078
Total liabilities and stockholders' equity	$ 422,599	$ 420,909

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

MOMENTA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Collaboration revenues:				
Product revenue	$ 2,579	$ 84,717	$ 43,960	$ 244,325
Research and development revenue	2,523	3,228	7,233	9,288
Total collaboration revenue	5,102	87,945	51,193	253,613
Operating expenses:				
Research and development*	20,233	16,307	58,805	43,418
General and administrative*	10,999	11,480	34,309	28,995
Total operating expenses	31,232	27,787	93,114	72,413
Operating (loss) income	(26,130)	60,158	(41,921)	181,200
Other income (expense):				
Interest income	308	194	950	498
Interest expense	—	(14)	—	(89)
Total other income	308	180	950	409
Net (loss) income	$ (25,822)	$ 60,338	$ (40,971)	$ 181,609
Net (loss) income per share:				
Basic	$ (0.51)	$ 1.21	$ (0.81)	$ 3.65
Diluted	$ (0.51)	$ 1.18	$ (0.81)	$ 3.58
Weighted average shares outstanding:				
Basic	50,500	50,034	50,365	49,759
Diluted	50,500	51,048	50,365	50,796
Comprehensive (loss) income	$ (25,637)	$ 60,130	$ (40,719)	$ 181,477

* Non-cash share-based compensation expense included in operating expenses is as follows:

Research and development	$ 1,530	$ 1,339	$ 4,317	$ 3,551
General and administrative	$ 2,019	$ 1,778	$ 5,943	$ 4,465

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

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

	Nine Months Ended September 30,	
	2012	2011
Cash Flows from Operating Activities:		
Net (loss) income	$ (40,971)	$ 181,609
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	5,387	4,249
Share-based compensation expense	10,260	8,016
Amortization of premium on investments	2,177	1,214
Loss on disposal of assets	3	35
Changes in operating assets and liabilities:		
Accounts receivable	23,220	(30,254)
Unbilled revenue	1,581	2,714
Prepaid expenses and other current assets	(1,017)	(1,217)
Restricted cash	(2,471)	1,778
Accounts payable	2,012	(1,839)
Accrued expenses	(1,182)	870
Deferred rent	24	(23)
Deferred revenue	29,191	(1,607)
Net cash provided by operating activities	28,214	165,545
Cash Flows from Investing Activities:		
Purchases of property and equipment	(14,613)	(5,780)
Purchases of marketable securities	(434,404)	(423,644)
Proceeds from maturities of marketable securities	454,751	236,880
Milestone payment related to developed technology	—	(6,664)
Purchase of equity investment	(400)	—
Net cash provided by (used in) investing activities	5,334	(199,208)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock under stock plans	2,104	4,889
Payments on financed leasehold improvements	—	(258)
Principal payments on capital lease obligations	—	(1,178)
Net cash provided by financing activities	2,104	3,453
Increase (decrease) in cash and cash equivalents	35,652	(30,210)
Cash and cash equivalents, beginning of period	49,245	100,681
Cash and cash equivalents, end of period	$ 84,897	$ 70,471
Supplemental Cash Flow Information:		
Cash paid for interest	$ —	$ 89

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

MOMENTA PHARMACEUTICALS, INC.
NOTES TO UNAUDITED, CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. The Company

Business

Momenta Pharmaceuticals, Inc. (the "Company" or "Momenta") was incorporated in the state of Delaware in May 2001 and began operations in early 2002. Its facilities are located in Cambridge, Massachusetts. Momenta is a biotechnology company specializing in the structural characterization, process engineering and biologic systems analysis of complex molecules. The Company's initial technology was built on the ability to characterize complex polysaccharides. Over the last decade, the Company has expanded its expertise into technologies that enable it to develop a diversified product portfolio of complex generic, follow-on biologic (FOB), and novel drugs. The Company presently derives all of its revenue from collaborations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company's accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, applicable to interim periods and, in the opinion of management, include all normal and recurring adjustments that are necessary to state fairly the results of operations for the reported periods. The Company's condensed consolidated financial statements have also been prepared on a basis substantially consistent with, and should be read in conjunction with, the Company's audited consolidated financial statements for the year ended December 31, 2011, which were included in the Company's Annual Report on Form 10-K that was filed with the Securities and Exchange Commission, or SEC, on February 28, 2012. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year.

The accompanying condensed consolidated financial statements reflect the operations of the Company and the Company's wholly-owned subsidiary Momenta Pharmaceuticals Securities Corporation. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and judgments, including those related to revenue recognition, accrued expenses, and share-based payments. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates.

Net (Loss) Income Per Common Share

The Company computes basic net (loss) income per common share by dividing net (loss) income by the weighted average number of common shares outstanding, which includes common stock issued as a result of public offerings, stock option exercises, stock purchased under the Company's employee stock purchase plan and vesting of shares of restricted common stock. The Company computes diluted net (loss) income per common share by dividing net (loss) income by the weighted average number of common shares and potential shares from outstanding stock options and unvested restricted stock determined by applying the treasury stock method.

The following table sets forth for the periods presented the Company's reconciliation of basic and diluted share amounts (in thousands, except per share amounts):

	For the Three Months Ended September 30, 2012	For the Three Months Ended September 30, 2011	For the Nine Months Ended September 30, 2012	For the Nine Months Ended September 30, 2011
Numerator:				
Net (loss) income	$ (25,822)	$ 60,338	$ (40,971)	$ 181,609
Denominator:				
Basic weighted average shares outstanding	50,500	50,034	50,365	49,759
Weighted average stock equivalents from assumed exercise of stock options and restricted stock awards	—	1,014	—	1,037
Diluted weighted average shares outstanding	50,500	51,048	50,365	50,796
Basic net (loss) income per share	$ (0.51)	$ 1.21	$ (0.81)	$ 3.65
Diluted net (loss) income per share	$ (0.51)	$ 1.18	$ (0.81)	$ 3.58
Weighted average anti-dilutive shares related to:				
Outstanding stock options	3,959	1,861	3,661	1,967
Restricted stock awards	1,179	820	1,048	564

For the three and nine months ended September 30, 2012, the effect of all potentially dilutive securities is anti-dilutive as the Company had a net loss during those periods. Accordingly, basic and diluted net loss per share is the same for the three and nine months ended September 30, 2012.

The weighted average anti-dilutive shares shown in the foregoing table were not included in the computation of diluted net (loss) income per share. In those reporting periods in which the Company has reported net income, anti-dilutive shares comprise those common stock equivalents that have either an exercise price above the average stock price for the period or average unrecognized share-based compensation expense related to the common stock equivalents that are sufficient to "buy back" the entire amount of shares. In those reporting periods in which the Company has a net loss, anti-dilutive shares comprise the impact of that number of shares that would have been dilutive had the Company had net income plus the number of common stock equivalents that would be anti-dilutive had the Company had net income. Furthermore, performance-based restricted common stock awards which vest based upon the United States Food and Drug Administration, or FDA, approval for M356, the Company's second major generic program, in the United States, were excluded from diluted shares outstanding as the vesting condition had not been met as of September 30, 2012.

Fair Value Measurements

In May 2011, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Codification, or ASC, Update No. 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs. Update No. 2011-04 clarifies the FASB's intent about the application of certain existing fair value measurement and disclosure requirements and changes certain principles or requirements for measuring or disclosing information about fair value. It requires, for all Level 3 fair value measurements, new quantitative information about significant unobservable inputs used. In January 2012, the Company adopted Update No. 2011-04. Update No. 2011-04 does not impact the Company's results of operations or financial position.

The following tables present information about the Company's assets that are measured at fair value on a recurring basis at September 30, 2012 and December 31, 2011, and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices (adjusted), interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. The fair value hierarchy level is determined by the lowest level of significant input. Financial assets measured at fair value on a recurring basis are summarized as follows (in thousands):

Description	Balance as of September 30, 2012	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 82,785	$ 82,785	$ —	$ —
Marketable securities:				
U.S. Government-sponsored enterprise obligations	50,981	—	50,981	—
Corporate debt securities	157,222	—	157,222	—
Commercial paper obligations	68,718	—	68,718	—
Total	$ 359,706	$ 82,785	$ 276,921	$ —

Description	Balance as of December 31, 2011	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 48,316	$ 45,316	$ 3,000	$ —
Marketable securities:				
U.S. Government-sponsored enterprise obligations	163,997	—	163,997	—
Corporate debt securities	64,245	—	64,245	—
Commercial paper obligations	63,245	—	63,245	—
Foreign government bond	6,705	—	6,705	—
U.S. Treasury obligation	1,001	1,001	—	—
Total	$ 347,509	$ 46,317	$ 301,192	$ —

In the tables above, as of September 30, 2012 and December 31, 2011, corporate debt securities include $7.5 million and $28.5 million, respectively, of Federal Deposit Insurance Corporation, or FDIC, guaranteed senior notes issued by financial institutions under the FDIC's Temporary Liquidity Guarantee Program.

During the nine months ended September 30, 2012, there were no transfers between Level 1 and Level 2 financial assets. The Company did not have any non-recurring fair value measurements on any assets or liabilities at September 30, 2012 and December 31, 2011. The carrying amounts reflected in the Company's condensed consolidated balance sheets for cash, accounts receivable, unbilled revenue, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term maturities.

Cash, Cash Equivalents and Marketable Securities

The Company invests its cash in bank deposits, money market accounts, corporate debt securities, United States treasury obligations, commercial paper and United States government-sponsored enterprise securities in accordance with its investment policy. The Company has established guidelines relating to diversification and maturities that allow the Company to manage risk.

The Company invests its excess cash balances in short-term and long-term marketable debt securities. The Company classifies its investments in marketable debt securities as available-for-sale based on facts and circumstances present at the time it purchased the securities. The Company reports available-for-sale investments at fair value at each balance sheet date and includes any unrealized holding gains and losses (the adjustment to fair value) in accumulated other comprehensive income (loss), a component of stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in interest income. To determine whether an other-than-temporary impairment exists, the Company considers whether it intends to sell the debt security and, if it does not intend to sell the debt security, it considers available evidence to assess whether it is more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. The Company reviewed its investments with unrealized losses and concluded that no other-than-temporary impairment existed at September 30, 2012 as it has the ability and intent to hold these investments to maturity and it is not more likely than not that it will be required to sell the security before the recovery of its amortized cost basis. The Company did not record any impairment charges related to its marketable securities during the three and nine months ended September 30, 2012 and 2011. The Company's marketable securities are classified as cash equivalents if the original maturity, from the date of purchase, is 90 days or less, and as marketable securities if the original maturity, from the

date of purchase, is in excess of 90 days. The Company's cash equivalents are composed of money market funds, United States government-sponsored enterprise obligations and commercial paper.

The Company's financial assets have been initially valued at the transaction price and subsequently valued at the end of each reporting period, typically utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches, and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. The Company did not adjust or override any fair value measurements provided by its pricing services as of September 30, 2012 and December 31, 2011.

The following tables summarize the Company's cash, cash equivalents and marketable securities at September 30, 2012 and December 31, 2011 (in thousands):

As of September 30, 2012	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 84,897	$ —	$ —	$ 84,897
U.S. Government-sponsored enterprise obligations				
Due in one year or less	11,750	—	—	11,750
Due in two years or less	39,209	27	(5)	39,231
Corporate debt securities				
Due in one year or less	83,781	23	(9)	83,795
Due in two years or less	73,352	92	(17)	73,427
Commercial paper obligations due in one year or less	68,658	63	(3)	68,718
Total	$ 361,647	$ 205	$ (34)	$ 361,818
Reported as:				
Cash and cash equivalents	$ 84,897	$ —	$ —	$ 84,897
Marketable securities	276,750	205	(34)	276,921
Total	$ 361,647	$ 205	$ (34)	$ 361,818

As of December 31, 2011	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 46,245	$ —	$ —	$ 46,245
U.S. Government-sponsored enterprise obligations				
Due in one year or less	53,730	10	(4)	53,736
Due in two years or less	110,344	11	(94)	110,261
Corporate debt securities				
Due in one year or less	63,224	12	(48)	63,188
Due in two years or less	1,060	—	(3)	1,057
Commercial paper obligations due in one year or less	66,193	52	—	66,245
Foreign government bond due in one year or less	6,722	—	(17)	6,705
U.S. Treasury obligations due in one year or less	1,001	—	—	1,001
Total	$ 348,519	$ 85	$ (166)	$ 348,438
Reported as:				
Cash and cash equivalents	$ 49,244	$ 1	$ —	$ 49,245
Marketable securities	299,275	84	(166)	299,193
Total	$ 348,519	$ 85	$ (166)	$ 348,438

At September 30, 2012, the Company held 18 marketable securities that were in a continuous unrealized loss position for less than one year. At December 31, 2011, the Company held 35 marketable securities that were in a continuous unrealized loss position for less than one year. At September 30, 2012 and December 31, 2011, no marketable securities were in a continuous unrealized loss position for greater than one year.

The unrealized losses were caused by fluctuations in interest rates. The following table summarizes the aggregate fair value of these securities at September 30, 2012 and December 31, 2011 (in thousands):

	As of September 30, 2012		As of December 31, 2011	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
U.S. Government-sponsored enterprise obligations	$ 3,001	$ (5)	$ 104,107	$ (98)
Corporate debt securities	$ 47,674	$ (26)	$ 36,582	$ (51)
Foreign government bond	$ —	$ —	$ 6,705	$ (17)
Commercial paper obligations	$ 4,992	$ (3)	$ —	$ —

Income Taxes

The Company generated U.S. taxable income during the years ended December 31, 2011 and 2010, and as a result, utilized $190.9 million and $26.3 million, respectively, of its available federal net operating loss carryforwards to offset this income. At December 31, 2011, the Company had federal and state net operating loss carryforwards of $25.3 million and $18.7 million, respectively, available to reduce future taxable income and which will expire at various dates through 2029. Of this amount, approximately $8.3 million of federal and state net operating loss carryforwards relate to stock option deductions for which the related tax benefit will be recognized in equity when realized. At December 31, 2011, the Company had federal and state research and development and other credit carryforwards of $4.9 million and $3.2 million, respectively, available to reduce future tax liabilities, which will expire at various dates beginning in 2017 through 2030. The 2011 amounts reported for utilization of available federal net operating loss carryforwards and federal and state net operating loss carryforwards available to reduce future taxable income reflect minor tax return adjustments that resulted from the Company's filing of its 2011 consolidated tax return in the third quarter 2012.

As of December 31, 2011, the Company had $2.8 million of gross unrecognized tax benefits, $2.7 million of which, if recognized, would impact the Company's effective tax rate. The difference between the total amount of the unrecognized tax benefits and the amount that would affect the effective tax rate consists of the federal tax benefit of state research and development credits.

In March 2012, the Company entered into a Tax Incentive Agreement with the Massachusetts Life Sciences Center ("MLSC") under the MLSC's Life Sciences Tax Incentive Program (the "Program") to expand life sciences-related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences in the Commonwealth of Massachusetts. The Program was established in 2008 in order to incentivize life sciences companies to create new sustained jobs in Massachusetts. Under the Tax Incentive Agreement, once the Company attains its job creation commitment, it expects to receive a job creation tax award in the amount of $1.2 million. Jobs must be maintained for at least five years, during which time a portion of the grant proceeds can be recovered by the Massachusetts Department of Revenue if the Company does not meet and maintain its job creation commitments. Once the Company attains the initial job creation commitment, it will recognize the award as other income in its consolidated statements of comprehensive (loss) income over the five year period the Company satisfies its job creation commitments.

Comprehensive (Loss) Income

In May 2011, the FASB issued ASC Update No. 2011-05, Comprehensive Income (Topic 820): Presentation of Comprehensive Income, which was further amended by ASC Update No. 2011-12, Comprehensive Income (Topic 220): Deferral of the effective date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05, issued in December 2011. Update No. 2011-05 requires that net income, items of other comprehensive income and total comprehensive income be presented in one continuous statement or two separate consecutive statements. The amendments in this Update also require that reclassifications from other comprehensive income to net income be presented on the face of the financial statements. In January 2012, the Company adopted Update No. 2011-05, with the exception of the presentation of reclassifications on the face of the financial statements, which has been deferred by the FASB until further notice. Update No. 2011-05 is related to presentation only and does not impact the Company's results of operations or financial position. See the unaudited condensed consolidated statements of comprehensive (loss) income for relevant disclosures.

3. Intangible Assets

As of September 30, 2012 and December 31, 2011, intangible assets, net of accumulated amortization, were as follows (in thousands):

	Weighted Average Amortization Period (in years)	As of September 30, 2012 Gross Carrying Amount	As of September 30, 2012 Accumulated Amortization	As of December 31, 2011 Gross Carrying Amount	As of December 31, 2011 Accumulated Amortization
Core and developed technology	10	$ 10,257	$ (3,281)	$ 10,257	$ (2,485)
Non-compete agreement	2	170	(170)	170	(170)
Total intangible assets	10	$ 10,427	$ (3,451)	$ 10,427	$ (2,655)

The Company's intangible assets are described in Note 7, *Related Party Transactions*.

Amortization is computed using the straight-line method over the useful lives of the respective intangible assets as there is no other pattern of use that is reasonably estimable. Amortization expense was approximately $0.3 million and $1.0 million for the three months ended September 30, 2012 and 2011, respectively. Amortization expense was approximately $0.8 million and $1.1 million for the nine months ended September 30, 2012 and 2011, respectively.

The Company expects to incur amortization expense of appropriately $1.1 million per year for each of the next five years.

4. Restricted Cash

The Company designated $17.5 million as collateral for a security bond posted in the litigation against Watson Pharmaceuticals Inc. ("Watson"), Amphastar Pharmaceuticals Inc. ("Amphastar") and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar). The $17.5 million is held in an escrow account by Hanover Insurance. The Company reclassified this restricted cash from current to long-term in the third quarter of 2012 as the timing of a final decision in the enoxaparin litigation is not known.

The Company designated $2.5 million as collateral for a letter of credit related to the lease of office and laboratory space at its headquarters located at 675 West Kendall Street, Cambridge, Massachusetts. This balance will remain restricted through the remaining term of the lease which ends in April 2015. The Company will earn interest on the balance.

5. Collaboration and License Agreements

2003 Sandoz Collaboration

In November 2003, the Company entered into a collaboration and license agreement (the "2003 Sandoz Collaboration") with Sandoz AG and Sandoz Inc. (collectively, "Sandoz") to jointly develop and commercialize enoxaparin sodium injection, a generic version of Lovenox®, a low molecular weight heparin or LMWH.

Under the 2003 Sandoz Collaboration, the Company granted Sandoz the exclusive right to manufacture, distribute and sell enoxaparin sodium injection in the United States. The Company agreed to provide development and related services on a commercially reasonable basis, which included developing a manufacturing process to make enoxaparin sodium injection, scaling up the process, contributing to the preparation of an Abbreviated New Drug Application, or ANDA, in Sandoz's name to be filed with the FDA, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee which is responsible for overseeing development, legal and commercial activities and which approves the annual collaboration plan. Sandoz is responsible for commercialization activities and will exclusively distribute and market the product. The Company identified two significant deliverables in this arrangement consisting of: (i) a license and (ii) development and related services. The Company determined that the license did not meet the criteria for separation as it did not have stand-alone value apart from the development services, which are proprietary to the Company. Therefore, the Company determined that a single unit of accounting exists with respect to the 2003 Sandoz Collaboration.

In July 2010, the FDA granted marketing approval of the ANDA for enoxaparin sodium injection filed by Sandoz. The Company is paid at cost for external costs incurred for development and related activities and is paid for full time equivalents, or FTEs, performing development and related services. The profit-share or royalties Sandoz is obligated to pay the Company under the 2003 Sandoz Collaboration differ depending on whether (i) there are no third-party competitors marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), (ii) a Lovenox-Equivalent Product is being marketed by Sanofi-Aventis, which distributes the brand name Lovenox, or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, or (iii) there is one or more third-party which is not Sanofi-Aventis marketing a Lovenox-Equivalent Product. Until October 2011, no third-party competitors were marketing a Lovenox-Equivalent Product; therefore, Sandoz paid the Company 45% of the contractual profits from the sale of enoxaparin sodium injection. Profits on sales of enoxaparin sodium injection are calculated by deducting from net sales the cost of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. In October 2011, Sandoz confirmed that an authorized generic Lovenox-Equivalent Product was being marketed, which meant that Sandoz was obligated to pay the Company a royalty on its net sales of enoxaparin sodium injection until the contractual profits from those net sales in a product year (July 1—June 30) reached a certain threshold, which was achieved in December 2011, at which point the Company reverted back to receiving profit share revenue. Additionally, in October 2011, FDA approved the ANDA for the enoxaparin product of Watson and Amphastar. In January 2012, following the Court of Appeals for the Federal Circuit granting a stay of the preliminary injunction previously issued against them by the United States District Court, Watson announced that it and Amphastar intended to launch their enoxaparin product. Consequently, Sandoz is obligated to pay the Company a royalty on net sales in each post-launch contract year, which for net sales up to a pre-defined sales threshold is payable at a 10% rate, and for net sales above the sales threshold increases to 12%. The Company earned $2.6 million in royalty revenue and $44.0 million in profit share/royalty revenue from Sandoz during the three and nine months ended September 30, 2012, respectively. The Company earned $74.7 million and $234.3 million in profit share product revenue from Sandoz during the three and nine months ended September 30, 2011, respectively.

In June 2012, the Company exercised its audit rights under the 2003 Sandoz Collaboration and engaged an independent audit firm to conduct an audit of Sandoz's reported product revenues for the product year July 1, 2011 to June 30, 2012. During the three month period ended March 31, 2012, the Company earned product revenue from Sandoz that was based on both a profit share and a royalty on Sandoz's reported net sales of enoxaparin. The audit identified $2.3 million of product revenue that had not previously been reported by Sandoz to the Company related to the three month period ended March 31, 2012, resulting in an understatement of the Company's product revenues for that period. The Company recorded this additional $2.3 million of product revenue in the three month period ended June 30, 2012.

If certain milestones were achieved with respect to enoxaparin sodium injection under certain circumstances, Sandoz agreed to make payments to the Company which would reach $55 million if all such milestones were achieved. Under the 2003 Sandoz Collaboration, in July 2010, upon the achievement of a regulatory milestone the Company earned and recognized $5.0 million in research and development revenue. In addition, no third-party competitors had marketed a Lovenox-Equivalent Product as of July 2011, the one year anniversary of the FDA's approval of enoxaparin sodium for injection. As a result, in the third quarter of 2011, the Company earned and recognized $10.0 million in product revenue upon the achievement of the commercial milestone. The Company is no longer eligible to receive milestones under the 2003 Sandoz Collaboration because the remaining milestones were contingent upon there being no third-party competitors marketing an interchangeable generic version of a Lovenox-Equivalent Product.

A portion of the development expenses and certain legal expenses, which in the aggregate have exceeded a specified amount, are offset against profit-sharing amounts, royalties and milestone payments. Sandoz also may offset a portion of any product liability costs and certain other expenses arising from patent litigation against any profit-sharing amounts, royalties and milestone payments.

The Company recognizes research and development revenue from FTE services and research and development revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs is recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such development and related services, except with respect to any amounts due Sandoz for manufacturing raw material purchases, which are recorded on a net basis as an offset to the related development expense. There have been no such manufacturing raw material purchases since 2006.

2006 Sandoz Collaboration

In July 2006, the Company entered into a Stock Purchase Agreement and an Investor Rights Agreement with Novartis Pharma AG, and in June 2007, the Company and Sandoz AG executed a definitive collaboration and license agreement (as amended, the "Second Sandoz Collaboration Agreement") related to the development and commercialization of M356, which is designed to be a generic version of Copaxone® (glatiramer acetate injection). Together, this series of agreements is referred to as the "2006 Sandoz Collaboration."

Pursuant to the terms of the Stock Purchase Agreement, the Company sold 4,708,679 shares of common stock to Novartis Pharma AG, an affiliate of Sandoz AG, at a per share price of $15.93 (the closing price of the Company's common stock on the NASDAQ Global Market was $13.05 on the date of the Stock Purchase Agreement) for an aggregate purchase price of $75.0 million, resulting in a paid premium of $13.6 million. The Company recognizes revenue from the $13.6 million paid premium on a straight-line basis over the estimated development period of approximately six years beginning in June 2007. The Company recognized research and development revenue relating to this paid premium of approximately $0.5 million for each of the three months ended September 30, 2012 and 2011. The Company recognized research and development revenue relating to this paid premium of approximately $1.6 million for each of the nine months ended September 30, 2012 and 2011. The portion of the equity premium that is unearned at September 30, 2012 is included in deferred revenue. Under the 2006 Sandoz Collaboration, the Company and Sandoz AG expanded the geographic markets for enoxaparin sodium injection covered by the 2003 Sandoz Collaboration to include the European Union and further agreed to exclusively collaborate on the development and commercialization of M356 for sale in specified regions of the world. Each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize such products for all medical indications in the relevant regions. The Company has agreed to provide development and related services which includes developing a manufacturing process to make the products, scaling up the process, contributing to the preparation of regulatory filings, further scaling up the manufacturing process to commercial scale, and related development of intellectual property. The Company has the right to participate in a joint steering committee, which is responsible for overseeing development, legal and commercial activities and which approves the annual collaboration plan. Sandoz AG is responsible for commercialization activities and will exclusively distribute and market any products covered by the 2006 Sandoz Collaboration. The Company identified two significant deliverables in this arrangement consisting of (i) a license and (ii) the development and related services. The Company determined that the license did not meet the criteria for separation as it does not have stand-alone value apart from the development services, which are proprietary to the Company. Therefore, the Company has determined that a single unit of accounting exists with respect to the 2006 Sandoz Collaboration.

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

Costs, including development costs and the cost of clinical studies, will be borne by the parties in varying proportions, depending on the type of expense and the related product. All commercialization responsibilities and costs will be borne by Sandoz AG. Under the 2006 Sandoz Collaboration, the Company is paid at cost for any external costs incurred in the development of products where development activities are funded solely by Sandoz AG or partly in proportion where development costs are shared between the Company and Sandoz AG. The Company also is paid at a contractually specified rate for FTEs performing development services where development activities are funded solely by Sandoz AG or partly by proportion where development costs are shared between the Company and Sandoz AG. The parties will share profits in varying proportions, depending on the product. The Company is eligible to receive up to $163.0 million in milestone payments upon the achievement of certain regulatory, commercial and sales-based milestones that include $10.0 million in regulatory milestones related to the approval by the FDA of M356 and $153.0 million in sales-based and commercial milestones. The Company has concluded that the regulatory milestones pursuant to its 2006 Sandoz Collaboration are substantive. The Company evaluated factors such as the scientific and regulatory risks that must be overcome to achieve the respective milestone, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Revenues from non-refundable regulatory milestones are recognized upon successful accomplishment of the milestones as research and development revenue. Sales-based and commercial milestones are accounted for as royalties and are recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. The Company has not earned and therefore has not recognized any milestone payments under this arrangement.

The Company recognizes research and development revenue from FTE services and research and development revenue from external development costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenue from external development costs is recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such development and related services, except with respect to any amounts due Sandoz for shared development costs, which are recorded on a net basis. The Company recorded a reduction in research and development revenue of zero and $0.3 million for the three and nine months ended September 30, 2012, respectively, related to the shared development costs. The Company recorded a reduction in research and development revenue of zero and $1.1 million for the three and nine months ended September 30, 2011, respectively, related to the shared development costs.

Baxter Agreement

In December 2011, the Company entered into a development, license and option agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, "Baxter"). The Baxter Agreement became effective in February 2012, following expiration of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as amended. The Company refers to this agreement as the "Baxter Agreement."

Under the Baxter Agreement, the Company agreed to collaborate, on a world-wide basis, on the development and commercialization of two follow-on biologics, or "FOBs", M923 and M834, products indicated in the inflammatory and autoimmune therapeutic areas, or the initial products. In addition, Baxter has the right, for a three year period, to select up to four additional FOBs to be included in the collaboration. In July 2012, Baxter selected a third FOB for inclusion in the collaboration. The Company initiated development of this product, a monoclonal antibody for oncology, which has been designated as M511. The Company does not receive milestones related to the selection of additional products. The process for achieving milestones is as follows:

- Baxter selects an additional product to the collaboration and the Company initiates development.
- If the Company achieves pre-defined "Minimum Development" criteria related to the additional product, Baxter is given an option to exercise exclusive license rights.
- If Baxter exercises its exclusive license option to advance the product under the Baxter Agreement, the Company will earn a license payment.
- If the Company achieves pre-defined "Technical Development" criteria related to the initial product or additional product, the Company will earn a milestone payment.
- For the initial and additional products, if the Company either (a) submits an Investigational New Drug application, or IND, to the FDA or (b) is not required to file an IND, either referred to as the "Transition Period," the Company will earn a milestone payment.
- Following the Transition Period, Baxter will assume responsibility for development of the FOBs, and the Company has the potential to receive up to $300 million in regulatory milestones. These milestones are designed to reward the Company, on a sliding scale, for reducing the scope of the clinical activities required to develop each FOB.

Under the Baxter Agreement, each party has granted the other an exclusive license under its intellectual property rights to develop and commercialize designated products for all therapeutic indications. The Company has agreed to provide development and related services on a commercially reasonable basis through the Transition Period for each product, which include high-resolution analytics, characterization, and product and process development. Baxter is responsible for clinical development, manufacturing and commercialization activities and will exclusively distribute and market any products covered by the Baxter Agreement. The Company has the right to participate in a joint steering committee, consisting of an equal number of members from the Company and Baxter, to oversee and manage the development and commercialization of products under the collaboration. Costs, including development costs, payments to third parties for intellectual property licenses, and expenses for legal proceedings, including the patent exchange process pursuant to the Biologics Price Competition and Innovation Act of 2009, will be borne by the parties in varying proportions, depending on the type of expense and the stage of development. The Company has the option to participate, at its discretion, in a cost and profit share arrangement for the four additional products up to 30%. If the profit share is elected, the royalties payable would be reduced by up to nearly half. Absent a cost share arrangement, the Company will generally be responsible for research and process development costs prior to filing an IND, and the cost of in-human clinical trials, manufacturing in accordance with current good manufacturing practices and commercialization will be borne by Baxter.

In addition, the Company has agreed, for a period commencing six months following the effective date and ending on the earlier of (i) three years from the effective date of the Baxter Agreement (subject to certain limited time extensions as provided for in the Baxter Agreement) or (ii) the selection of the four additional products, to notify Baxter of bona fide offers from third parties to develop or commercialize an FOB that could be an additional product candidate. Following such notification, if Baxter does not select such proposed product or products for inclusion in the collaboration, the Company has the right to develop, manufacture, and commercialize such product or products on its own or with a third party. The Company also agreed to provide Baxter with a right of first negotiation with respect to collaborating in the development of a competing product for a period of three years following the effectiveness of an IND exemption or waiver or regulatory authority authorization to dose humans, subject to certain restrictions as outlined in the Baxter Agreement. Following the third anniversary of the effective date of the Baxter Agreement (subject to certain limited time extensions as provided for in the Baxter Agreement), the Company may develop, on its own or with a third party, any follow-on biologic products not named under the Baxter Agreement, subject to certain restrictions.

Under the terms of the Baxter Agreement, the Company received an initial cash payment of $33 million. The Company is eligible to receive from Baxter license payments totaling $28 million for the exercise of options with respect to the additional four product candidates that can be named under the Baxter Agreement, payments of $5 million each for extensions of the period during which such additional products may be selected, and a license payment of $7 million upon the achievement of pre-defined "Minimum Development" criteria, as defined in the agreement, for M834 (a selected FOB). The Company is also eligible to receive from Baxter an aggregate of approximately $380 million in potential milestone payments, comprised of (i) up to $80 million in substantive milestone payments upon achievement of specified technical and development milestone events across the six product candidates, and (ii) regulatory milestones totaling up to $300 million, on a sliding scale, across the six product candidates where, based on the products' regulatory application, there is a significant reduction in the scope of the clinical trial program required for regulatory approval. Two of the technical and development milestones were time-based and the total eligible milestones have been adjusted to correspond to current development plans. There are no other time-based milestones included in the Baxter Agreement. The

technical and development milestones include (i) achievement of certain criteria that will ultimately drive commercial feasibility for manufacturing the products and (ii) acceptance by the FDA of an IND application.

The first anticipated technical and development milestone is $6 million and is due to the Company upon achievement of technical criteria for one of the products under the collaboration. The anticipated timing of this milestone is 2014.

In addition, if any of the six products are successfully developed and launched, Baxter will be required to pay to the Company royalties on net sales of licensed products worldwide, with a base royalty rate in the high single digits with the potential for significant tiered increases based on the number of competitors, the interchangeability of the product, and the sales tier for each product. The maximum royalty with all potential increases would be slightly more than double the base royalty.

The term of the collaboration shall continue throughout the development and commercialization of the products, on a product-by-product and country-by-country basis, until there is no remaining payment obligation with respect to a product in the relevant territory, unless earlier terminated by either party pursuant to the terms of the Baxter Agreement.

The Baxter Agreement may be terminated by:

- either party for breach by or bankruptcy of the other party;
- the Company in the event Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products within a certain time period;
- Baxter for its convenience; or
- the Company in the event Baxter does not exercise commercially reasonable efforts to commercialize a product in the United States or other specified countries, provided that we also have certain rights to directly commercialize such product, as opposed to terminating the Baxter Agreement, in event of such a breach by Baxter.

In accordance with FASB's ASC Update No. 2009-13: Multiple-Deliverable Revenue Arrangements (Topic 615), the Company identified all of the deliverables at the inception of the Baxter Agreement. The deliverables were determined to include (i) the development and product licenses to the two initial FOBs and the four additional FOBs, (ii) the research and development services related to the two initial FOBs and the four additional FOBs and (iii) the Company's participation in a joint steering committee. The Company has determined that each of the license deliverables do not have stand-alone value apart from the related research and development services deliverables as there are no other vendors selling similar, competing products on a stand-alone basis, Baxter does not have the contractual right to resell the license, and Baxter is unable to use the license for its intended purpose without the Company's performance of research and development services. As such, the Company determined that separate units of accounting exist for each of the six licenses together with the related research and development services, as well as the joint steering committee with respect to this arrangement. The estimated selling prices for these units of accounting were determined based on similar license arrangements and the nature of the research and development services to be performed for Baxter and market rates for similar services. The arrangement consideration of $61 million, which includes the $33 million upfront payment and aggregate option payments of $28 million, was allocated to the units of accounting based on the relative selling price method. Of the $61 million, $10.3 million has been allocated to the first initial product license together with the related research and development services, $10.3 million to each of the four additional product licenses with the related research and development services, $9.4 million has been allocated to the second initial product license together with the related research and development services due to that product's stage of development at the time the license was delivered, and $114,000 has been allocated to the joint steering committee unit of accounting. The Company will commence revenue recognition for each of the six units of accounting related to the products upon delivery of the related development and product license and will record this revenue on a straight-line basis over the applicable performance period during which the research and development services will be delivered. The Company will recognize the revenue related to the joint steering committee deliverable over the applicable performance period during which the research and development services will be delivered. The Company has determined that the performance period for each of the combined six units of accounting consisting of the products and related research and development services, begins upon delivery of the related development and product license and ends upon FDA approval of the related product. The Company has also determined that the applicable performance period for the joint steering committee deliverable begins upon delivery of the first development and product license and ends upon the latest date of FDA approval. The Company currently estimates that the performance period for the two Initial Products, considering their respective stage of development, is approximately five and seven years, respectively, and the period of performance for the joint steering committee is approximately nine years. As of September 30, 2012, the Company has commenced recognition of the revenue allocated to the two initial products but not for the four additional products as those licenses have not been delivered. The Company recognized revenue relating to the amortized portion of the upfront payment of approximately $0.8 million and $2.2 million for the three and nine months ended September 30, 2012, respectively. The portion of the upfront payment that is unearned at September 30, 2012 is included in deferred revenue.

Any associated royalty or profit sharing payments will be considered contingent fees that will be recorded as earned in future periods. Baxter's option to extend the naming period is considered to be substantive. As such, potential fees associated with the naming period extensions will be recognized in future periods if and when Baxter exercises its right to extend the naming period for any additional products.

The Company has concluded that all of the technical, development and regulatory milestones pursuant to the Baxter Agreement are substantive. The Company evaluated factors such as the scientific and regulatory risks that must be overcome to achieve these milestones, the level of effort and investment required and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Revenues from non-refundable technical, development and regulatory milestones will be recognized upon successful accomplishment of the milestones as research and development revenue. The Company has not earned and therefore has not recognized any milestone payments under this arrangement.

Massachusetts Institute of Technology

The Company has two patent license agreements with the Massachusetts Institute of Technology ("M.I.T.") that grant the Company various exclusive and nonexclusive worldwide licenses, with the right to grant sublicenses, under certain patents and patent applications relating to methods and technologies for analyzing and characterizing sugars and certain heparins, heparinases and other enzymes and synthesis methods. Subject to typical retained rights of M.I.T. and the United States government, the Company was granted exclusive rights under certain of these patents and applications in certain fields.

The Company must meet certain diligence requirements in order to maintain the licenses under the two agreements. Under the agreements, the Company must expend at least $1.0 to $1.2 million per year towards the research, development and commercialization of products and processes covered by the agreements. In addition, the Company is obligated to make first commercial sales and meet certain minimum sales thresholds of products or processes including, under the amended and restated license agreement, a first commercial sale of a product or process no later than June 2013 and minimal sales of products thereafter ranging from $0.5 million to $5.0 million annually. M.I.T. may convert the exclusive licenses under the amended and restated license agreement to non-exclusive licenses, as its sole remedy, if the Company fails to meet its diligence obligations. Under the license agreement covering sequencing machines, M.I.T. has the right to treat a failure by the Company to fulfill its diligence obligations as a material breach of the license agreement.

In exchange for the licenses granted in the two agreements, the Company has paid M.I.T. license issue fees and annual aggregate license and maintenance fees of $157,500. The Company is also required to pay M.I.T. royalties on certain products and services covered by the licenses and sold by the Company or its affiliates or sublicensees, a percentage of certain other income received by the Company from corporate partners and sublicensees, and certain patent prosecution and maintenance costs.

The following table summarizes the license, maintenance and royalties recorded (in thousands):

	For the Three Months Ended September 30, 2012	For the Three Months Ended September 30, 2011	For the Nine Months Ended September 30, 2012	For the Nine Months Ended September 30, 2011
License and maintenance fees	$ 39	$ 39	$ 143	$ 118
Royalty fees	201	2,900	954	6,000
Total	$ 240	$ 2,939	$ 1,097	$ 6,118

The Company granted Sandoz a sublicense under the amended and restated license agreement with M.I.T to certain of the patents and patent applications licensed to the Company. If M.I.T. converts the Company's exclusive licenses under this agreement to non-exclusive licenses due to the Company's failure to meet diligence obligations, or if M.I.T. terminates this agreement, M.I.T. will honor the exclusive nature of the sublicense the Company granted to Sandoz so long as Sandoz continues to fulfill its obligations to the Company under the collaboration and license agreement the Company entered into with Sandoz and, if the Company's agreement with M.I.T. is terminated, Sandoz agrees to assume the Company's rights and obligations to M.I.T.

6. Share-Based Payments

2004 Stock Incentive Plan

The Company's 2004 Stock Incentive Plan, as amended, allows for the granting of incentive and nonstatutory stock options, restricted stock awards, stock appreciation rights and other share-based awards to employees, officers, directors, consultants and advisors. At December 31, 2011, the Company was authorized to issue up to 13,369,141 shares of common stock with annual increases (to be added on the first day of the Company's fiscal years during the period beginning in fiscal year 2005 and ending on the second day of fiscal year 2013) equal to the lowest of (i) 1,974,393 shares, (ii) 5% of the then outstanding number of common shares or (iii) such other amount as the Board of Directors may authorize. Effective January 1, 2012, the Company's Board of Directors increased the number of authorized shares by 1,974,393 shares. At September 30, 2012, the Company had 6,250,096 shares available for grant under the 2004 Stock Incentive Plan.

Share-Based Compensation Expense

Total compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the Company's employee stock purchase plan for the three months ended September 30, 2012 and 2011 was $3.5 million and $3.1 million, respectively. Total compensation cost for all share-based payment arrangements, including employee, director and consultant stock options, restricted stock and the Company's employee stock purchase plan for the nine months ended September 30, 2012 and 2011 was $10.3 million and $8.0 million, respectively.

Share-based compensation expense related to outstanding employee stock option grants and the Company's employee stock purchase plan was $2.0 million and $1.7 million for the three months ended September 30, 2012 and 2011, respectively. Share-based compensation expense related to outstanding employee stock option grants and the Company's employee stock purchase plan was $5.7 million and $4.9 million for the nine months ended September 30, 2012 and 2011, respectively. During the nine months ended September 30, 2012, the Company granted 1,088,151 stock options, of which 697,875 were granted in connection with annual merit awards, 248,276 were granted to new hires, and 142,000 were granted to members of the Company's Board of Directors. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended September 30, 2012 and 2011 was $8.35 and $10.66 per option, respectively. The weighted average grant date fair value of option awards granted during the nine months ended September 30, 2012 and 2011 was $9.20 and $9.28 per option, respectively.

The following tables summarize the weighted average assumptions the Company used in its fair value calculations at the date of grant:

	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	For the Three Months Ended September 30, 2012	For the Three Months Ended September 30, 2011	For the Three Months Ended September 30, 2012	For the Three Months Ended September 30, 2011
Expected volatility	67%	67%	66%	76%
Expected dividends	—	—	—	—
Expected life (years)	6.5	6.5	0.5	0.5
Risk-free interest rate	1.1%	1.6%	0.1%	0.2%

	Weighted Average Assumptions			
	Stock Options		Employee Stock Purchase Plan	
	For the Nine Months Ended September 30, 2012	For the Nine Months Ended September 30, 2011	For the Nine Months Ended September 30, 2012	For the Nine Months Ended September 30, 2011
Expected volatility	66%	68%	66%	75%
Expected dividends	—	—	—	—
Expected life (years)	6.3	6.3	0.5	0.5
Risk-free interest rate	1.3%	2.8%	0.1%	0.2%

At September 30, 2012, the total remaining unrecognized compensation cost related to nonvested stock option awards amounted to $12.3 million, including estimated forfeitures, which will be recognized over the weighted average remaining requisite service period of 2.6 years.

During the nine months ended September 30, 2012, holders of options issued under the Company's stock plans exercised their right to acquire an aggregate of 184,409 shares of common stock. Additionally, during the nine months ended September 30, 2012, the Company issued 54,789 shares of common stock to employees under the Company's employee stock purchase plan.

Restricted Stock Awards

The Company has also made awards of restricted common stock to employees, officers and directors. During the nine months ended September 30, 2012, the Company awarded 134,892 shares of restricted common stock to its officers in connection with its annual merit grant, which generally fully vest over the four years following the grant date. During the nine months ended September 30, 2012, the Company awarded 58,890 shares of performance-based restricted common stock to newly hired employees of the Company. The performance condition for these awards is the approval in the United States from the FDA for M356, the Company's second major generic program, provided that approval occurs on or before March 28, 2015. As of September 30, 2012, the Company has granted 943,290 shares of unvested restricted common stock tied to this M356 performance condition to its employees and officers. The awards of restricted common stock are generally forfeited if the employment relationship terminates with the Company prior to vesting.

The Company recorded share-based compensation expense related to outstanding restricted stock awards, including the performance-based shares, because the Company determined that it was probable the performance condition would be achieved, of $1.6 million and $1.3 million for

the three months ended September 30, 2012 and 2011, respectively. The Company recorded share-based compensation expense related to outstanding restricted stock awards, including the performance-based shares, because the Company determined that it was probable the performance condition would be achieved, of $4.5 million and $3.1 million for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012, the total remaining unrecognized compensation cost related to nonvested restricted stock awards amounted to $9.4 million, which is expected to be recognized over the weighted average remaining requisite service period of 1.8 years.

A summary of the status of nonvested shares of restricted stock as of September 30, 2012 and the changes during the nine months then ended are presented below (in thousands, except per share amounts):

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2012	1,107	$ 14.29
Granted	193	15.14
Vested	(115)	12.66
Forfeited	(16)	14.56
Nonvested at September 30, 2012	1,169	$ 14.59

Nonvested shares of restricted stock that have time-based or performance-based vesting schedules as of September 30, 2012 are summarized below:

Vesting Schedule	Nonvested Shares
Time-based	286
Performance-based	883
Nonvested at September 30, 2012	1,169

7. Related Party Transactions

In April 2007, the Company entered into an asset purchase agreement, or the Purchase Agreement, with Parivid, LLC, or Parivid, a provider of data integration and analysis services to the Company, and S. Raguram, the principal owner and Chief Technology Officer of Parivid. Parivid is considered to be a related party because a co-founder and former member of the Company's Board of Directors is the brother of S. Raguram. Pursuant to the Purchase Agreement, the Company acquired patent rights, software, know-how and other intangible assets, and assumed certain specified liabilities, of Parivid related to the acquired assets in exchange for $2.5 million in cash paid at closing and up to $11.0 million in contingent milestone payments in a combination of cash and/or stock in the manner and on the terms and conditions set forth in the Purchase Agreement.

In July 2011, the Company entered into an Amendment to the Purchase Agreement pursuant to which the parties agreed that a milestone payment would be made in cash rather than through the issuance of Company stock. In August 2011, the Company paid Parivid $6.7 million in cash, in lieu of stock, pursuant to this Amendment as consideration for the completion and satisfaction of a milestone related to the enoxaparin sodium injection developed technology that was achieved in July 2011. The Company capitalized the payment as developed technology, which is included in intangible assets in the condensed consolidated balance sheets. The developed technology is being amortized over the estimated useful life of the enoxaparin sodium injection developed technology of approximately 10 years.

8. Legal Contingencies

In August 2008, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against the Company and Sandoz in the United Stated Federal District Court in the Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for M356. The suit alleges infringement related to four of the seven Orange Book patents listed for Copaxone. The Company and Sandoz asserted defenses of non-infringement, invalidity and unenforceability and filed counterclaims for declaratory judgments to have all seven of the Orange Book patents as well as two additional patents in the same patent family adjudicated in the present lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book patents listed for Copaxone, and in October 2010, the court consolidated the Mylan case with the case against the Company and Sandoz. A trial on the issue of inequitable conduct occurred in July 2011 and the trial on the remaining issues occurred in September 2011 in the consolidated case. In June 2012, the Court issued its opinion and found all of the claims in the patents to be valid, enforceable and infringed. In July 2012, the Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. The Orange Book patents and one non-Orange book patent expire in May 2014 and one non-Orange Book patent expires in September 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35

U.S.C. section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz or Mylan ANDA prior to the expiration of the Orange Book patents. In July 2012, the Company appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in October 2012, the Company and Mylan filed their appellate briefs.

In December 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and the Company for patent infringement related to certain other non-Orange Book patents after Teva's motion to add those patents to the ongoing Paragraph IV litigation was denied. In January 2010, the Company and Sandoz filed a motion to dismiss this second suit on several grounds, including the failure of Teva to state an actionable legal claim and lack of subject matter jurisdiction. The motion is pending. The Company intends to defend this suit.

If the decision in the first suit is not reversed on appeal, or the Company is not successful in its second suit, the final approval and launch of M356 could be significantly delayed until expiration of the relevant patent rights which could impair its ability to commercialize M356 and the Company's business could be materially harmed. Litigation involves many risks and uncertainties, and there is no assurance that Novartis AG, Sandoz or the Company will prevail in either lawsuit. At this time, the Company believes a loss is not probable.

In September 2011, the Company and Sandoz sued Amphastar, Watson and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in the United States District Court for the District of Massachusetts for infringement of two of the Company's patents. Also in September, 2011, the Company filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar, Watson and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the court granted the Company's motion for a preliminary injunction and entered an order enjoining Amphastar, Watson and International Medical Systems, Ltd. from advertising, offering for sale or selling their enoxaparin sodium product in the United States until the conclusion of a trial on the merits and required the Company and Sandoz to post a security bond of $100 million to maintain the preliminary injunction. Amphastar, Watson and International Medical Systems, Ltd. filed a notice to appeal the decision and an emergency motion to dissolve or stay the preliminary injunction. In January 2012, the CAFC granted the motion to stay the preliminary injunction, pending appeal. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding the case to the District Court. In September 2012, the Company filed a petition with the CAFC for a rehearing by the full court *en banc*. The collateral for the security bond posted in the litigation remains outstanding. In the event that the Company is not successful in appealing the CAFC decision and loses the case at the District Court, and Amphastar and Watson are able to prove they suffered damages as a result of the preliminary injunction, the Company could be liable for damages for up to $35 million of the security bond. In June 2012, Amphastar filed a motion to increase the amount of the security bond, which the Company and Sandoz have opposed. Proceedings in the District Court have been stayed pending the outcome of the appellate proceedings.

While the Company intends to vigorously prosecute this action against Watson and Amphastar, and believes that it can ultimately prove its case in court, this suit could last a number of years. As a result, potential recovery of lost profits and damages could await a final judgment after an appeal of a District Court decision. Litigation involves many risks and uncertainties, and there is no assurance that the Company or Sandoz will prevail in this patent enforcement suit.

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

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

Statements contained or incorporated by reference in this Quarterly Report Form 10-Q that are not based on historical fact are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements regarding future events and our future results are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management including, without limitation, our expectations regarding results of operations, general and administrative expenses, research and development expenses, current and future development and manufacturing efforts, regulatory filings, clinical trial results and the sufficiency of our cash for future operations. Forward-looking statements can be identified by terminology such as "anticipate," "believe," "could," "could increase the likelihood," "hope," "target," "project," "goals," "potential," "predict," "might," "estimate," "expect," "intend," "is planned," "may," "should," "will," "will enable," "would be expected," "look forward," "may provide," "would" or similar terms, variations of such terms or the negative of those terms.

We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Such factors that could cause or contribute to such differences include those factors discussed below under Item 1A of Part II "Risk Factors." 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.

Business Overview

The Company

We are a biotechnology company specializing in the structural characterization, process engineering and biologic systems analysis of complex molecules such as polysaccharides, polypeptides, and biologics (including proteins and antibodies). Our initial technology was built on the ability to characterize complex polysaccharides. Over the last decade, we have expanded our expertise into technologies that enable us to develop a diversified product portfolio of complex generic, follow-on biologic (FOB), and novel drugs. Our business strategy has been to develop both generic and novel drugs, and we are working with collaborators to develop and commercialize our complex generics and follow-on biologics. This strategy was validated by the marketing approval and commercial launch of enoxaparin sodium injection, a generic version of Lovenox®, in July 2010. Since its launch through September 30, 2012, we have recorded enoxaparin sodium injection product revenues of approximately $400 million, driven primarily by its initial status as a sole generic. We believe that our scientific capabilities, engineering approaches, intellectual property and regulatory strategies, and unique business model position us to develop and commercialize competitively differentiated products in our target areas of complex generics, follow-on biologics and novel drugs.

Our Programs

Our complex generic programs target marketed products that were originally approved by the United States Food and Drug Administration, or FDA, as New Drug Applications, or NDAs. Therefore, we are able to access the existing 505(j) generic regulatory pathway and submitted Abbreviated New Drug Applications, or ANDAs, for these products. Our first commercial product, enoxaparin sodium injection, which we developed and commercialized in collaboration with Sandoz, an affiliate of Novartis AG, received FDA marketing approval in July 2010 as a generic version of Lovenox. Lovenox is a complex mixture of polysaccharide chains derived from naturally sourced heparin which is used to prevent and treat deep vein thrombosis, or DVT, and to support the treatment of acute coronary syndromes, or ACS. The enoxaparin ANDA submitted by our collaborative partner Sandoz was the first ANDA for a generic Lovenox to be approved by FDA, validating our novel approaches to the structural characterization, process engineering and biologic systems analysis of complex molecules such as Lovenox. From July 2010 through early October 2011, the enoxaparin sodium injection marketed by Sandoz was the sole generic version of Lovenox, and consequently, under the terms of our collaborative agreement with Sandoz, we earned a substantial profit share on Sandoz's net sales of enoxaparin. In developing our enoxaparin product, we filed for patent protection for certain of our enoxaparin-related technology and we have sought, and continue to seek, to enforce our issued patents.

Our second complex generic product candidate, M356, is designed to be a generic version of Copaxone® (glatiramer acetate injection), a drug that is indicated for the reduction of the frequency of relapses in patients with relapsing-remitting multiple sclerosis, or RRMS. Copaxone consists of a synthetic mixture of polypeptide chains. With M356, we extended our core polysaccharide characterization and process engineering capabilities to develop capabilities for the structural characterization, process engineering and biologic systems analysis of this complex polypeptide mixture. We are also collaborating with Sandoz to develop and commercialize M356, and the Sandoz ANDA for M356 is currently under FDA review. In our development of M356 we filed for patent protection for certain of our M356-related technology, and if necessary, we may seek to enforce issued patents relating to our M356 product.

Our FOB program is targeted toward developing biosimilar versions of marketed therapeutic proteins, with a goal of obtaining FDA designation as interchangeable. In March 2010, an abbreviated regulatory process was codified in Section 351(k) of the Patient Protection and Affordable Care Act of 2010. This new pathway opens the market for biosimilar and interchangeable versions of a broad array of biologic therapeutics, including antibodies, cytokines, fusion proteins, hormones and blood factors. Forecasters predict a rapidly growing multi-billion dollar global market for these products. Most of these biologic therapeutics are complex mixtures, and for several years we have been investing in developing novel approaches to the structural characterization, process engineering and analysis of the biologic activities of these therapeutics. In February 2012, FDA released three documents containing their preliminary guidelines for applications under the Section 351(k) pathway. These guidelines state that FDA will use a step-wise review that considers the totality-of-the-evidence in determining extent of the clinical development program. This approach puts a substantial emphasis on structural and functional characterization data in evaluating biosimilar products for approval. We believe the framework that the FDA has outlined in the draft guidance documents aligns with our strategy for FOBs. Our goal is to engineer biologic therapeutics that will show minimal to no structural or functional differences from the reference brand product, thereby justifying a more selective and targeted approach to human clinical testing to support demonstration of biosimilarity and interchangeability.

Our novel therapeutics program leverages the capabilities and expertise built during the development of our complex generics and FOB programs to address unmet clinical needs. Our most advanced efforts have been in the area of polysaccharide mixtures. M402, in Phase 1 clinical development as a potential anti-cancer agent, is a novel heparan sulfate mimetic that binds to multiple growth factors, adhesion molecules and chemokines to inhibit tumor angiogenesis, progression, and metastasis. Our other polysaccharide-based drug candidate, adomiparin, has been engineered to possess what we believe will be an improved therapeutic profile compared to other currently marketed anticoagulants to support the treatment of ACS. We have no plans to move forward with further clinical trials of adomiparin unless we have a collaborator for that program. In addition to these two development candidates, we are also seeking to discover and develop additional novel drugs. Our goal is to leverage the multi-targeting nature of complex mixture molecules to develop novel therapeutics which could positively modulate multiple pathways in a disease. We believe that our core technology platform will enable us to map the critical nodes that regulate complex diseases. We will then be able to define the optimal therapeutic intervention to target the appropriate nodes. We have built significant capabilities in biological characterization and engineering of proteins through our FOB platform that provide us with the potential to create unique and novel formulations of protein and antibody drug compositions for specific disease indications. To add to these capabilities, in December 2011, we acquired selected assets of Virdante Pharmaceuticals, Inc. relating to “sialic switch” technology. Sialic acid is a type of sugar modification on selected proteins that is understood to regulate anti-inflammatory and immunomodulatory functions of these proteins. These assets add to our core ability to modify and engineer protein backbones to precisely regulate biological networks and develop novel biologic product candidates.

Our Collaborations

In 2003, we entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration, with Sandoz N.V. and Sandoz Inc. to jointly develop, manufacture and commercialize enoxaparin sodium injection. Sandoz N.V. later assigned its rights in the 2003 Sandoz Collaboration to Sandoz AG, an affiliate of Novartis Pharma AG. We refer to Sandoz AG and Sandoz Inc. together as Sandoz.

In 2006 and 2007, we entered into a series of agreements, including a Stock Purchase Agreement and an Investor Rights Agreement, with Novartis Pharma AG, and a collaboration and license agreement, or the Second Sandoz Collaboration Agreement, with Sandoz AG. Together, this series of agreements is referred to as the 2006 Sandoz Collaboration. Under the Second Sandoz Collaboration Agreement, we and Sandoz AG jointly develop, manufacture and commercialize M356. In connection with the 2006 Sandoz Collaboration, we sold 4,708,679 shares of common stock to Novartis Pharma AG at a per share price of $15.93 (the closing price of our common stock on the NASDAQ Global Market was $13.05 on the date of purchase) for an aggregate purchase price of $75.0 million, resulting in an equity premium of $13.6 million.

Prior to the launch of enoxaparin sodium injection in 2010, the collaboration revenues derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration primarily consisted of amounts earned by us for reimbursement by Sandoz of research and development services and development costs. In July 2010, Sandoz began the commercial sale of enoxaparin sodium injection. The profit-share or royalties Sandoz is obligated to pay us under the 2003 Sandoz Collaboration differ depending on whether (i) there are no third-party competitors marketing an interchangeable generic version of Lovenox, or Lovenox-Equivalent Product (as defined in the 2003 Sandoz Collaboration), (ii) a Lovenox-Equivalent Product is being marketed by Sanofi-Aventis, which distributes the brand name Lovenox, or licensed by Sanofi-Aventis to another company to be sold as a generic drug, both known as authorized generics, or (iii) there is one or more third-party competitors which is not Sanofi-Aventis marketing a Lovenox-Equivalent Product. From July 2010 through September 2011, no third-party competitor was marketing a Lovenox-Equivalent Product; therefore, during that period, Sandoz paid us 45% of the contractual profits from the sale of enoxaparin sodium injection. In September 2011, FDA approved the ANDA for the enoxaparin product of Amphastar Pharmaceuticals, Inc. or Amphastar. In October 2011, Sandoz confirmed that an authorized generic Lovenox-Equivalent Product was being marketed, which meant that Sandoz was obligated to pay us a royalty on its net sales of enoxaparin sodium injection until the contractual profits from those net sales in a product year (July 1—June 30) reached a certain threshold. Upon the achievement of the contractual profit threshold in December 2011, Sandoz was obligated to pay us a profit share for the remainder of the product year. In January 2012, following the Court of Appeals for the Federal Circuit granting a stay of the preliminary injunction previously issued by the United States District Court, Watson Pharmaceuticals, Inc., or Watson, and Amphastar launched their third-party competitor enoxaparin product. Consequently, in each product year, for net sales of enoxaparin up to a pre-defined sales threshold, Sandoz is obligated to pay us a royalty on net sales payable at a 10% rate, and for net sales above the sales threshold, payable at a 12% rate.

Certain development and legal expenses may reduce the amount of profit-share, royalty and milestone payments paid to us by Sandoz. Any product liability costs and certain other expenses arising from patent litigation may also reduce the amount of profit-share, royalty and milestone payments paid to us by Sandoz, but only up to 50% of these amounts due to us from Sandoz each quarter. Our contractual share of these development and legal expenses is subject to an annual adjustment in each of the next four years, but the amount of any future payment due to the annual adjustment is not expected to be material. The second annual adjustment of $3.9 million was recorded as a reduction in collaboration product revenue in the three months ended June 30, 2012.

In December 2011, we and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, collectively Baxter, entered into a global collaboration and license agreement, or the Baxter Agreement, to develop and commercialize up to six FOBs. The Baxter Agreement became effective in February 2012. Baxter is an established healthcare company with global product development, manufacturing and commercial capabilities. To accelerate efforts in the FOB space and address this growing global market, we expect to significantly increase the headcount in 2012 and related operating expenses dedicated to our FOB program in both 2012 and 2013. We expect that the increase in operating expenses will be partially offset in future years by revenues from option fees and milestone payments under the Baxter Agreement, subject to achievement of technical and regulatory criteria.

As of September 30, 2012, we had an accumulated deficit of $144.4 million. To date, we have devoted substantially all of our capital resource expenditures to the research and development of our product candidates. In the second half of 2010, we began to derive revenue from our profit share on the commercial sale of enoxaparin sodium injection. Due to the launch by Watson and Amphastar of an enoxaparin sodium injection product in January 2012, our enoxaparin product revenue has significantly decreased. Depending on the future outcome of enoxaparin litigation, we may incur annual operating losses over the next several years as we expand our drug commercialization, development and discovery efforts. 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 revenue to return to profitability.

Financial Operations Overview

Revenue

Our revenue has been primarily derived from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration. In 2012, we began recognizing revenue under the Baxter Agreement. In the near term, our current and future revenues are dependent upon the continued sale by Sandoz of enoxaparin sodium injection, payments earned under the Baxter Agreement and potential profit share payments and milestones from our 2006 Sandoz Collaboration. In the longer term, our revenue growth will depend upon the successful clinical development, regulatory approval and launch of new commercial products and the pursuit of external business development opportunities. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the amount and timing of revenue we earn under our collaborative or strategic relationships.

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, clinical trial costs, contract research and manufacturing costs and the costs of laboratory equipment and facilities. We expense research and development costs as incurred. Due to the variability in the length of time necessary to develop a product, the uncertainties related to the estimated cost of the projects and ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the ultimate cost to bring our product candidates to market are not available.

Product Programs—Complex Generic and Follow-On Biologics

Enoxaparin sodium injection—Generic Lovenox®

Lovenox is distributed worldwide by Sanofi-Aventis U.S. LLC, or Sanofi-Aventis, and is also known outside the United States as Clexane® and Klexane®. Under our 2003 Sandoz Collaboration, we work with Sandoz exclusively to develop, manufacture and commercialize enoxaparin sodium injection in the United States and Sandoz is responsible for funding substantially all of the United States-related enoxaparin sodium injection development, regulatory, legal and commercialization costs, other than legal expenses incurred by each party in connection with the patent suits filed against Teva Pharmaceutical Industries Ltd., or Teva, in December 2010 and Amphastar and Watson in September 2011. In these cases, Momenta and Sandoz each bear their own legal expenses.

Sandoz submitted ANDAs in its name to the FDA for enoxaparin sodium injection in syringe and vial forms, seeking approval to market enoxaparin sodium injection in the United States. The ANDA for the syringe form of enoxaparin sodium injection was approved in July 2010 and the ANDA for the vial form of enoxaparin sodium injection was approved in December 2011.

In September 2011, we and Sandoz sued Amphastar, Watson and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in the United States District Court for the District of Massachusetts for infringement of two of our patents. Also in September 2011, we filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar, Watson and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the court granted our motion for a preliminary injunction and entered an order enjoining Amphastar, Watson and International Medical Systems, Ltd. from advertising, offering for sale or

selling their enoxaparin sodium product in the United States until the conclusion of a trial on the merits and requiring us and Sandoz to post a security bond of $100 million in connection with the litigation. Amphastar, Watson and International Medical Systems, Ltd. appealed the decision to the CAFC, and in January 2012, the CAFC stayed the preliminary injunction, pending a decision on appeal. In June 2012, Amphastar filed a motion to increase the amount of the security bond, which we and Sandoz have opposed. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding the case to the District Court. In September 2012, we filed a petition with the CAFC for rehearing by the full court *en banc*. Proceedings in the District Court have been stayed pending the outcome of the appellate proceedings.

In December 2010, we sued Teva in the United States District Court for the District of Massachusetts for infringement of two of our patents. Proceedings in this case have been stayed pending the outcome of the appellate proceedings in the Amphastar case.

M356—Generic Copaxone® (glatiramer acetate)

In North America, Copaxone is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva. In Europe, Copaxone is marketed by Teva and Sanofi-Aventis. Under the 2006 Sandoz Collaboration, we and Sandoz AG agreed to exclusively collaborate on the development and commercialization of M356 and two other follow-on products for sale in specified regions of the world.

Under the 2006 Sandoz Collaboration, costs, including development costs and the costs of clinical studies, will be borne by the parties in varying proportions depending on the type of expense and the related product. For M356, we are generally responsible for all of the development costs in the United States. For M356 outside of the United States and for enoxaparin sodium injection in the European Union, we share development costs in proportion to our profit sharing interest. All commercialization responsibilities and costs will be borne by Sandoz AG worldwide as they are incurred for all products. We are reimbursed at cost for any full-time equivalent employee expenses as well as any external costs incurred in the development of products to the extent development costs are born by Sandoz AG. Sandoz AG is responsible for funding all of the legal expenses incurred under the 2006 Collaboration; however a portion of certain legal expenses will be offset against the profit-sharing amounts in proportion to our profit sharing interest.

In December 2007, Sandoz submitted to the FDA an ANDA in its name seeking approval to market M356 in the United States containing a Paragraph IV certification. This is a certification by the ANDA applicant that the patent relating to the drug product that is the subject of the ANDA is invalid or unenforceable or will not be infringed. In July 2008, the FDA notified Sandoz that it had accepted the ANDA for review as of December 27, 2007. In addition, the FDA's published database indicates that the first substantially complete ANDA submitted for glatiramer acetate injection containing a Paragraph IV certification was filed on December 27, 2007, making Sandoz's ANDA eligible for the grant of a 180-day generic exclusivity period upon approval. Under applicable laws, there are a number of ways an ANDA applicant may forfeit its 180-day exclusivity, including if the applicant fails to achieve at least tentative approval within 30 months after the date on which the ANDA is filed. Because tentative approval for the M356 ANDA was not received in the specified 30 months, the 180-day exclusivity period will be forfeited unless the exception to the forfeiture rule applies. We will not know whether the exception applies unless and until the FDA approves the ANDA. The review of Sandoz's ANDA is ongoing. We and Sandoz are in regular communication with the FDA to address any additional questions or requests that it may have as it continues the review of Sandoz's application.

Subsequent to FDA's acceptance of the ANDA for review, in August 2008, Teva and related entities and Yeda Research and Development Co., Ltd., filed suit against us and Sandoz in the United States Federal District Court in the Southern District of New York. The suit alleges infringement related to four of the seven Orange Book patents listed for Copaxone. We and Sandoz asserted defenses of non-infringement, invalidity and unenforceability and filed counterclaims for declaratory judgments to have all seven of the Orange Book patents as well as two additional patents in the same patent family adjudicated in the present lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book patents listed for Copaxone, and in October 2010, the court consolidated the Mylan case with the case against us and Sandoz. A trial on the issue of inequitable conduct occurred in July 2011 and the trial on the remaining issues occurred in September 2011 in the consolidated case. In June 2012, the Court issued its opinion and found all of the claims in the patents to be valid, enforceable and infringed. In July 2012, the Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. The Orange Book patents and one non-Orange book patent expire in May 2014 and one non-Orange Book patent expires in September 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35 U.S.C. section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz or Mylan ANDA prior to the expiration of the Orange Book patents. In July 2012, we appealed the decision to the CAFC, and in October 2012, we and Mylan filed appellate briefs.

In December 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and us for patent infringement related to certain other non-Orange Book patents after Teva's motion to add those patents to the ongoing Paragraph IV litigation was denied. In January 2010, we and Sandoz filed a motion to dismiss this second suit on several grounds, including the failure of Teva to state an actionable legal claim and lack of subject matter jurisdiction. The motion is pending. We intend to defend this suit.

If the decision in the first suit is not reversed on appeal, or we are not successful in the second suit, the final approval and launch of M356 could be significantly delayed until expiration of the relevant patent rights which could impair its ability to commercialize M356 and our business could be materially harmed. Litigation involves many risks and uncertainties, and there is no assurance that Novartis AG, Sandoz or we will prevail in either lawsuit.

Follow-On Biologics (FOBs)

We are also applying our technology platform to the development of biosimilar versions of marketed therapeutic proteins, with a goal of obtaining FDA designation as interchangeable. Therapeutic proteins represent a sizable segment of the United States drug industry, with sales expected to be approximately $60 billion in 2012. Given the inadequacies of standard technology, many of these therapeutic proteins have not been thoroughly characterized. Most of these products are complex glycoprotein mixtures, consisting of proteins that contain branched sugars that vary from molecule to molecule. These sugars can impart specific biological properties to the therapeutic protein and can often comprise a significant portion of the mass of the molecule. In addition to the structural characterization of several marketed therapeutic proteins, we are also advancing our structure-process capabilities as we further define the relationship between aspects of the manufacturing process and the structural composition of the final protein product. We believe that our investment in our analytics and characterization technology coupled with our investment in the science of better understanding the relationship of the biologic manufacturing process to structural composition provides us with the opportunity develop a competitive advantage for our future FOB product candidates.

In December 2011, we and Baxter entered into the Baxter Agreement under which we agreed to collaborate, on a world-wide basis, on the development and commercialization of up to six FOB products. The Baxter Agreement became effective in February 2012.

Most protein drugs have been approved by the FDA under the Biologics License Application, or BLA, regulatory pathway. The BLA pathway was created to review and approve applications for biologics that are typically produced from living systems. Until 2010, there was no abbreviated regulatory pathway for the approval of interchangeable or biosimilar versions of BLA-approved products in the United States; however, there have been guidelines for biosimilar products in the European Union for several years.

In March 2010, with the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCI, an abbreviated pathway for the approval of FOBs was created. The new abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable," based on its similarity to an existing brand product.

Under the BPCI, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original brand product was approved under a BLA. There are many biologics at this time for which this 12-year period has expired or is nearing expiration. We believe that scientific progress in the analysis and characterization of complex mixture drugs is likely to play a significant role in FDA's approval of biosimilar (including interchangeable) biologics in the years to come.

In December 2011, the FDA released its proposed biosimilar user fee program which includes a fee-based meeting process for consultation between applicants and the division of FDA responsible for reviewing biosimilar and interchangeable biologics applications under the new approval pathway. It contemplates well-defined meetings where the applicant can propose and submit analytic, physicochemical and biologic characterization data along with a proposed development plan. The proposed development plan may have a reduced scope of clinical development based on the nature and extent of the characterization data. There are defined time periods for meetings and written advice. In February 2012, the FDA published draft guidance documents for the development and registration of biosimilars and interchangeable biologics. The draft guidance documents indicate that the FDA will consider the totality of the evidence developed by an applicant in determining the nature and extent of the nonclinical and clinical requirements for a biosimilar or interchangeable biologic product.

The new law is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning will be subject to uncertainty for years to come.

Product Candidates—Novel Drugs

M402

M402 is a novel heparan sulfate mimetic that binds to multiple growth factors, adhesion molecules, and chemokines to inhibit tumor angiogenesis, progression, and metastasis. The use of heparins to treat venous thrombosis in cancer patients has generated numerous reports of antitumor activity; however, the dose of these products has been limited by their anticoagulant activity. M402, which is derived from unfractionated heparin, has been engineered to have significantly reduced anticoagulant activity while preserving the relevant antitumor properties of heparin.

Researchers have conducted a series of preclinical experiments using different pancreatic cancer models to test the hypothesis that M402 can modulate tumor progression and metastasis and enhance the efficacy of gemcitabine, a first-line standard of care chemotherapy treatment for pancreatic cancer. The preclinical results showed that M402 in combination with gemcitabine prolonged survival and substantially lowered the incidence of metastasis. M402 has the potential to complement conventional chemotherapy. Additionally, as M402 binds to multiple heparin binding factors involved in tumor growth and metastasis, it can play a role in a broad range of cancers.

In April 2012, we initiated a Phase 1/2 proof-of-concept clinical study in patients with advanced metastatic pancreatic cancer. The Phase 1/2 trial consists of two parts and will evaluate the safety, efficacy, pharmacokinetics and pharmacodynamics of M402 in combination with gemcitabine. Part A of the study is an open-label, multiple ascending dose escalation. Data from Part A are expected next year. Pending successful completion of this phase, we expect to initiate Part B of the trial, which will be a randomized, controlled study investigating the safety and antitumor activity of M402 administered in combination with gemcitabine compared with gemcitabine alone.

Adomiparin

Our other novel drug candidate, adomiparin, has been engineered to possess what we believe will be an improved therapeutic profile compared with other currently marketed anticoagulants to support the treatment of ACS. We have no plans to move forward with further clinical trials of adomiparin unless we have a collaborator for the program.

Discovery Program

We believe our core analytical tools enable new insights into exploring the biology of many diseases, which will lead to an enhanced understanding of the relative role of different biological targets and related cell-to-cell signaling pathways. Many complex diseases are a result of multiple biological activities. Our goal is to leverage the multi-targeting nature of complex mixture molecules to develop novel therapeutics which could positively modulate multiple pathways in a disease. We believe that our core technology platform will enable us to map the critical nodes that regulate complex diseases and then use the appropriate collection of "drugs"—whether polysaccharides, proteins, peptides or monoclonal antibodies—to target the appropriate nodes simultaneously. This unique approach could potentially expand the number of targets or pathways within a variety of diseases that could be rationally modulated.

General and Administrative

General and administrative expenses consist primarily of salaries and other related costs for personnel in executive, finance, legal, accounting, investor relations, information technology, 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, royalties and other general expenses.

Results of Operations

Three Months Ended September 30, 2012 and 2011

Collaboration Revenue

Collaboration revenue includes product revenue and research and development revenue earned under our collaborative arrangements. Product revenue consists of profit share/royalties earned from Sandoz on sales of enoxaparin sodium injection following its commercial launch in July 2010. For the three months ended September 30, 2011, we earned a profit share of $74.7 million on Sandoz's reported net sales of enoxaparin of $258.7 million. For the three months ended September 30, 2012, we earned a royalty of $2.6 million on Sandoz's reported net sales of enoxaparin of $33.8 million. The decrease in product revenue of $72.1 million, or 97%, and net sales of $224.9 million, or 87%, from the 2011 period to the 2012 period is primarily due to a change in the contractual basis of our earned product revenues from profit share to royalty-based following the launch of an authorized generic in October 2011 and the January 2012 launch of a third-party competitor's generic Lovenox®. Additionally, the decrease in product revenue and net sales from the 2011 period to the 2012 period is attributed to aggressive competitor pricing, significant adjustments to reserve accruals caused by increased competition and continued pricing pressure, and a decrease in units sold during the third quarter. In the three months ended September 30, 2011, we recorded revenue of $10.0 million due to the achievement of a commercial milestone under the 2003 Sandoz Collaboration as a result of enoxaparin sodium injection reaching the one-year anniversary from launch as the sole generic on the market.

Research and development revenue consists of amounts earned by us under the 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs, amounts earned by us under the 2006 Sandoz Collaboration for amortization of the equity premium and reimbursement of research and development services and reimbursement of development costs, and revenue earned by us under the Baxter Agreement for amortization of an upfront payment. Research and development revenue for the three months ended September 30, 2012 was $2.5 million, compared with $3.2 million for the three months ended September 30, 2011. The decrease in research and development revenue of $0.7 million, or 22%, from the 2011 period to the 2012 period is primarily due to a decrease in reimbursable manufacturing expenses associated with our M356 program offset by amortization of the upfront payment from Baxter.

We expect research and development revenue earned by us under the 2003 and 2006 Sandoz Collaborations will be between $1.0 million and $2.0 million per quarter and amortization of the equity premium will be approximately $0.5 million per quarter for the remainder of 2012. We will continue to amortize the $33.0 million upfront payment from Baxter over the development period of up to six FOBs with quarterly amortization totaling approximately $0.8 million for the remainder of 2012.

There are a number of factors that make it difficult for us to predict the magnitude of future enoxaparin sodium injection product revenue, including the impact of generic competition on the Sandoz market share; the pricing of products that compete with enoxaparin sodium injection and other actions taken by our competitors; the inventory levels of enoxaparin sodium injection maintained by wholesalers, distributors and other customers; the frequency of re-orders by existing customers; and the change in estimates for product reserves. Accordingly, our enoxaparin sodium injection product revenue in previous quarters may not be indicative of future enoxaparin sodium injection product revenue. The change in Sandoz contractual payment obligations, along with additional generic competition, has caused and will continue to cause our revenue from enoxaparin sodium injection to be significantly reduced compared to 2011.

Research and Development Expense

Research and development expense for the three months ended September 30, 2012 was $20.2 million, compared with $16.3 million for the three months ended September 30, 2011. The increase of $3.9 million, or 24%, from the 2011 period to the 2012 period resulted from increases of: $1.9 million in personnel and related costs associated with our headcount growth to support our programs; $1.1 million in facility-related expenses, principally due to increased rent and operating costs for our headquarters and the commencement in the first quarter of 2012 of a short-term sublease for expansion space; $0.9 million in depreciation expense primarily due to increased capital expenditures to support our programs; $0.5 million in laboratory expenses in support of our programs; $0.4 million in clinical trial costs for our M402 Phase 1/2 proof-of-concept clinical study; and $0.2 million in share-based compensation expense due to our headcount growth. These increases were offset by decreases of $0.7 million in amortization expense primarily due to the amortization of a 2011 milestone payment in connection with a 2007 asset purchase and $0.5 million primarily due to the timing of process development activities, manufacturing and third-party research costs related to our M356 program. We expect future research and development expenses to increase in support of our development efforts for our product candidates.

The following table summarizes the primary components of our research and development expenditures for our principal commercial and development programs for the three months ended September 30, 2012 and 2011 and the total external costs (including amortization) incurred by us for each of our major commercial and development projects (amounts in thousands). Certain prior period amounts have been reclassified to conform to the current period presentation. The table excludes costs incurred by our collaborative partner on such major commercial and development projects. We do not maintain or evaluate, and therefore do not allocate, internal research and development costs on a project-by-project basis. Consequently, we do not analyze internal research and development costs by project in managing our research and development activities.

	Research and Development Expense		
Commercial and Development Programs (Status)	**Three Months Ended September 30, 2012**	**Three Months Ended September 30, 2011**	**Project Inception to September 30, 2012**
Enoxaparin sodium injection (ANDA approved July 2010)	$ 437	$ 317	$ 51,177
M356 (ANDA Filed)	816	1,700	43,873
Adomiparin (Phase 2a)	3	1	35,866
M402 (Phase 1/2)	679	1,060	12,015
FOBs (Development)	2,243	211	8,693
Discovery programs	307	955	
Research and development internal costs	15,748	12,063	
Total research and development expense	$ 20,233	$ 16,307	

Enoxaparin sodium injection external expenditures remained consistent from the 2011 period to the 2012 period due to commercial activity being contracted directly with Sandoz. The decrease of $0.9 million in M356 external expenditures from the 2011 period to the 2012 period was primarily due to the timing of process development activities, manufacturing and third-party research costs. Adomiparin external expenditures remained insignificant from the 2011 period to the 2012 period reflecting our decision to not move forward with further clinical trials unless we have a collaborative partner for this program. The decrease of $0.4 million in M402 external expenditures from the 2011 period to the 2012 period was due to the timing of manufacturing and preclinical activities required to initiate the Phase 1/2 proof-of-concept clinical study. The increase of $2.0 million in FOB external expenditures from the 2011 period to the 2012 period was due to the timing of process development and third-party research costs to fund the build-out of our biologics infrastructure to support our Baxter Agreement. Discovery program external expenditures decreased by $0.6 million from the 2011 period to the 2012 period due to the timing of our research collaborations associated with these programs.

Research and development internal costs consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation. The increase of $3.7 million from the 2011 period to the 2012 period was due to additional research and development headcount and related costs in support of our development programs.

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

General and Administrative

General and administrative expense for the three months ended September 30, 2012 was $11.0 million, compared to $11.5 million for the three months ended September 30, 2011. General and administrative expense decreased by $0.5 million, or 4%, from the 2011 period to the 2012 period due to a decrease of $3.0 million in royalty fees payable primarily to Massachusetts Institute of Technology (M.I.T.) due to reduced enoxaparin product revenue caused by the loss of enoxaparin exclusivity, and by a change in the basis of our earned enoxaparin sodium injection product revenues from profit share to royalty-based. This decrease was offset by increases of: $1.4 million in professional fees principally due to increased legal fees relating to enoxaparin litigation; $0.5 million in personnel and related costs associated with our headcount growth; $0.2 million in facility-related expenses principally due to increased rent and operating costs for our headquarters and the commencement in the first quarter of 2012 of a short-term sublease for expansion space; $0.2 million in share-based compensation expense due primarily to increased headcount; and $0.2 million in other general and administrative expense for an insurance bond premium relating to enoxaparin litigation.

We expect our general and administrative expenses, including internal and external legal and business development costs that support our various product development efforts, to vary from period to period in relation to our commercial and development activities.

Interest Income and Expense

Interest income was $0.3 million and $0.2 million for the three months ended September 30, 2012 and 2011, respectively. The increase of $0.1 million from the 2011 period to the 2012 period was primarily due to higher average investment balances.

Interest expense was zero and $14,000 for the three months ended September 30, 2012 and 2011, respectively, because we repaid all borrowings on our equipment line of credit during 2011.

Nine Months Ended September 30, 2012 and 2011

Collaboration Revenue

For the nine months ended September 30, 2011, we earned a profit share of $234.3 million on Sandoz's reported net sales of enoxaparin of $789.7 million. For the nine months ended September 30, 2012, we earned $44.0 million in part on a profit share and in part on a royalty of Sandoz's reported net sales of enoxaparin of $365.8 million. The decrease in product revenue of $190.3 million, or 81%, and net sales of $423.9 million, or 54%, from the 2011 period to the 2012 period is primarily due to a change in the basis of our earned product revenues from profit share to royalty-based following the launch of an authorized generic in October 2011 and the launch of a third-party competitor enoxaparin in January 2012. Additionally, the decrease in product revenue and net sales from the 2011 period to the 2012 period is attributed to aggressive competitor pricing, significant adjustments to reserve accruals caused by increased competition and continued pricing pressure, and a decrease in units sold. In the nine months ended September 30, 2011, we recorded revenue of $10.0 million due to the achievement of an enoxaparin market exclusivity commercial milestone under the 2003 Sandoz Collaboration. In the nine months ended September 30, 2012 and 2011, we recorded a reduction in product revenue of $3.9 million and $3.7 million, respectively, for an annual adjustment to our contractual share of certain development and legal expenses.

Research and development revenue consists of amounts earned by us under the 2003 Sandoz Collaboration for reimbursement of research and development services and reimbursement of development costs, amounts earned by us under the 2006 Sandoz Collaboration for amortization of the equity premium and reimbursement of research and development services and reimbursement of development costs, and revenue earned by us under the Baxter Agreement for amortization of an upfront payment. Research and development revenue for the nine months ended September 30, 2012 was $7.2 million, compared with $9.3 million for the nine months ended September 30, 2011.The decrease in research and development revenue of $2.1 million, or 23%, from the 2011 period to the 2012 period is primarily due to a decrease in reimbursable manufacturing expenses associated with our M356 program offset by amortization of the upfront payment from Baxter and M356 shared development costs.

Research and Development Expense

Research and development expense for the nine months ended September 30, 2012 was $58.8 million, compared with $43.4 million for the nine months ended September 30, 2011. The increase of $15.4 million, or 35%, from the 2011 period to the 2012 period resulted from increases of: $4.7 million in personnel and related costs associated with our headcount growth to support our programs; $3.8 million in facility-related expenses, principally due to increased rent and operating costs for our headquarters and the commencement in the first quarter of 2012 of a short-term sublease for expansion space; $2.4 million in laboratory expenses in support of our programs; $1.8 million in depreciation and amortization expense primarily due to increased capital expenditures to support our programs; $1.4 million in clinical trial expenses associated with our M402 Phase 1/2 clinical study; $0.8 million in share-based compensation expense associated with our headcount growth and the amortization of performance-based restricted stock grants; and $0.3 million in process development and third-party research costs related to our FOB program. We expect future research and development expenses to increase in support of our product candidates.

The following table summarizes the primary components of our research and development expenditures for our principal commercial and development programs for the nine months ended September 30, 2012 and 2011 and the total external costs (including amortization) incurred by us for each of our major commercial and development projects (amounts in thousands). Certain prior period amounts have been reclassified to

conform to the current period presentation. The table excludes costs incurred by our collaborative partner on such major commercial and development projects. We do not maintain or evaluate, and therefore do not allocate, internal research and development costs on a project-by-project basis. Consequently, we do not analyze internal research and development costs by project in managing our research and development activities.

	Research and Development Expense		
Commercial and Development Programs (Status)	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Project Inception to September 30, 2012
Enoxaparin sodium injection (ANDA approved July 2010)	$ 1,217	$ 1,164	$ 51,177
M356 (ANDA Filed)	3,191	4,748	43,873
Adomiparin (Phase 2a)	41	86	35,866
M402 (Phase 1/2)	2,664	2,313	12,015
FOBs (Development)	4,695	584	8,693
Discovery programs	862	1,681	
Research and development internal costs	46,135	32,842	
Total research and development expense	$ 58,805	$ 43,418	

Enoxaparin sodium injection external expenditures remained consistent from the 2011 period to the 2012 period due to commercial activity being contracted directly with Sandoz. The decrease of $1.6 million in M356 external expenditures from the 2011 period to the 2012 period was primarily due to timing of process development activities, manufacturing and third-party research costs. Adomiparin external expenditures remained insignificant from the 2011 period to the 2012 period reflecting our decision to not move forward with further clinical trials unless we have a collaborative partner for this program. The increase of $0.4 million in M402 external expenditures from the 2011 period to the 2012 period was principally due to costs incurred in connection with the initiation of a Phase 1/2 proof-of-concept clinical study. The increase of $4.1 million in FOB external expenditures from the 2011 period to the 2012 period was due to the timing of process development and third-party research costs to fund the build-out of our biologics infrastructure to support our Baxter Agreement. Discovery program external expenditures decreased by $0.8 million from the 2011 period to the 2012 period due to the timing of our research collaborations associated with these programs.

Research and development internal costs consist of compensation and other expense for research and development personnel, supplies and materials, facility costs and depreciation. The increase of $13.3 million from the 2011 period to the 2012 period was due to additional research and development headcount and related costs in support of our development programs.

General and Administrative

General and administrative expense for the nine months ended September 30, 2012 was $34.3 million, compared to $29.0 million for the nine months ended September 30, 2011. General and administrative expense increased by $5.3 million, or 18%, from the 2011 period to the 2012 period due to increases of: $6.0 million in professional fees principally due to increased legal fees relating to enoxaparin litigation; $1.6 million in personnel and related costs associated with our headcount growth; $1.5 million in share-based compensation expense principally associated with increased headcount and the amortization of performance-based restricted stock grants; $0.9 million in facility-related expenses principally due to increased rent and operating costs for our headquarters and the commencement in the first quarter of 2012 of a short-term sublease for expansion space; and $0.4 million in other general and administrative expense for an insurance bond premium relating to enoxaparin litigation and renewals of vendor maintenance agreements. These increases were offset by a decrease of $5.2 million in royalty fees payable primarily to M.I.T. due to reduced enoxaparin product revenue caused by the loss of enoxaparin exclusivity, and by a change in the basis of our earned enoxaparin sodium injection product revenues from profit share to royalty-based.

Interest Income and Expense

Interest income was $1.0 million and $0.5 million for the nine months ended September 30, 2012 and 2011, respectively. The increase of $0.5 million from the 2011 period to the 2012 period was primarily due to higher average investment balances.

Interest expense was zero and $0.1 million for the nine months ended September 30, 2012 and 2011, respectively, because we repaid all borrowings on our equipment line of credit during 2011.

Liquidity and Capital Resources

We have financed our operations since inception primarily through the sale of equity securities, payments from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, including profit share/royalty payments related to sales of enoxaparin sodium injection, and borrowings from our lines of credit and capital lease obligations. Since our inception, we have received $405.9 million through private and public issuance of equity securities, including the issuance of shares to Novartis Pharma AG in connection with our 2006 Sandoz Collaboration. As of

September 30, 2012, we had received a cumulative total of $543.8 million from our 2003 Sandoz Collaboration and 2006 Sandoz Collaboration, a $33.0 million upfront payment under the Baxter Agreement, $4.0 million from debt financing, $9.2 million from capital lease obligations and $3.2 million from our landlord for leasehold improvements related to our corporate facility and additional funds from interest income. The January 2012 launch of a third-party competitor's enoxaparin sodium injection triggered a change in the basis of our product revenue from profit share to a royalty based on net sales of enoxaparin sodium injection. This competition and the resulting contractual change has had and will continue to have a negative impact on our near term cash generation trend. Our return to profitability, if at all, will most likely come from the commercialization of our generic Copaxone product, which is subject to FDA approval and litigation that could delay FDA approval. We expect to finance our current programs and planned operating requirements principally through our current cash, cash equivalents and marketable securities. We believe that these funds will be sufficient to meet our operating requirements through at least 2015. 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. For example, additional business development activities could increase our cash requirements. We may, from time to time, seek additional funding through a combination of new collaborative agreements, strategic alliances and additional equity and debt financings or from other sources.

At September 30, 2012, we had $361.8 million in cash, cash equivalents and marketable securities and $5.0 million in accounts receivable. In addition, we also held approximately $20.0 million in restricted cash, of which $17.5 million serves as collateral for a security bond posted in the litigation against Watson, Amphastar and International Medical Systems, Ltd. Our funds at September 30, 2012 were primarily invested in senior debt of government-sponsored enterprises, commercial paper, corporate debt securities and United States money market funds, directly or through managed funds, with remaining maturities of 24 months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of our evaluation of conditions in the financial markets, the maturity of specific investments, and our near term liquidity needs. We do not believe that our cash equivalents and marketable securities were subject to significant risk at September 30, 2012.

During the nine months ended September 30, 2012 and 2011, our operating activities provided cash of $28.2 million and $165.5 million, respectively. The cash provided by operating activities generally approximates our net (loss) income adjusted for non-cash items and changes in operating assets and liabilities.

For the nine months ended September 30, 2012, our net loss adjusted for non-cash items was $23.1 million. For the nine months ended September 30, 2012, non-cash items include share-based compensation of $10.3 million, depreciation and amortization of our property, equipment and intangible assets of $5.4 million and amortization of purchased premiums on our marketable securities of $2.2 million. In addition, the net change in our operating assets and liabilities provided cash of $51.4 million and resulted from a decrease in accounts receivable of $23.2 million, due to a contractual change in the basis of calculating our enoxaparin product revenue, related to the launch of a competitor's generic Lovenox in January 2012, aggressive competitor pricing, significant adjustments to reserve accruals caused by increased competition and continued pricing pressure, and a decrease in units sold; a decrease in unbilled revenue of $1.6 million, resulting from lower reimbursable manufacturing activities for our M356 program; an increase in prepaid expenses and other current assets of $1.0 million, primarily due to advance payments made for renewals of vendor maintenance agreements and interest accrued on our available-for-sale marketable debt securities; an increase in restricted cash of $2.5 million due to the designation of this cash as collateral for a letter of credit related to the lease of office and laboratory space at its headquarters located at 675 West Kendall Street; an increase in accounts payable of $2.0 million, primarily due to the timing of enoxaparin litigation expenses and process development activities for our FOB programs; a decrease in accrued expenses of $1.2 million resulting from the timing of M.I.T. royalty payments; and an increase in deferred revenue of $29.2 million, primarily due to the $33.0 million upfront payment under the Baxter Agreement.

For the nine months ended September 30, 2011, our net income adjusted for non-cash items was $195.1 million. For the nine months ended September 30, 2011, non-cash items include share-based compensation of $8.0 million, depreciation and amortization of our property, equipment and intangible assets of $4.2 million and amortization of purchased premiums on our marketable securities of $1.2 million. In addition, the net change in our operating assets and liabilities used cash of $29.6 million and resulted from: an increase in accounts receivable of $30.3 million, due to an increase in our quarterly profit-share for sales of enoxaparin sodium injection; a decrease in unbilled revenue of $2.7 million, resulting from decreased reimbursable manufacturing activities for our M356 program; an increase in prepaid expenses and other current assets of $1.2 million, due to advance payments made for nonclinical program studies, the renewal of vendor maintenance agreements, and an increase in interest accrued on our available-for-sale marketable debt securities; a decrease in restricted cash of $1.8 million due to the expiration of a letter of credit for our facility lease; a decrease in accounts payable of $1.8 million, primarily due to the timing of manufacturing activities for our M356 program and the timing of payments to vendors for purchases of laboratory equipment; an increase in accrued expenses of $0.9 million resulting from an increase in accrued royalties related to our profit-share for sales of enoxaparin sodium injection; and a decrease in deferred revenue of $1.6 million, due to the amortization of the $13.6 million equity premium paid by Novartis Pharma AG in connection with the 2006 Sandoz Collaboration.

During the nine months ended September 30, 2012, our investing activities provided cash of $5.3 million. In the first nine months of 2012, we used $434.4 million of cash to purchase marketable securities and we received $454.8 million from maturities of marketable securities. During the first nine months of 2012, we used $14.6 million, $9.2 million for the purchase of laboratory equipment for our FOB and novel drug programs, $3.1 million principally for leasehold improvements related to our headquarters and software for our business operations, and $2.3 million primarily for leasehold improvements, furniture and computer equipment related to additional leased laboratory and office space.

During the nine months ended September 30, 2011, our investing activities used cash of $199.2 million. In the first nine months of 2011, we used $423.6 million of cash to purchase marketable securities and we received $236.9 million from maturities of marketable securities. Additionally, in the first nine months of 2011, we paid Parivid $6.7 million as consideration for the completion and satisfaction of a milestone related to our enoxaparin sodium injection developed technology and $5.8 million to purchase laboratory equipment and leasehold improvements to support our programs.

During the nine months ended September 30, 2012, financing activities provided cash of $2.1 million in the form of net proceeds from stock option exercises and purchases of common shares through our employee stock purchase plan. During the nine months ended September 30, 2011, financing activities provided cash of $3.5 million in the form of net proceeds of $4.9 million from stock option exercises and purchases of common shares through our employee stock purchase plan. These proceeds were offset by principal payments of $1.2 million on our capital lease agreement obligations and $0.3 million on financed leasehold improvements related to our corporate headquarters.

Contractual Obligations

Our major outstanding contractual obligations relate to license maintenance obligations including royalties payable to third parties 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, 2011 have not materially changed since we filed that report.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of revenues and expenses during the reporting periods. Additionally, we are required to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the balance sheet dates. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, accrued expenses and share-based payments. 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.

Please read Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Annual Report on Form 10-K for the year ended December 31, 2011 for a discussion of our critical accounting policies and estimates.

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 United States money market, government-secured, 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. However, due to the conservative nature of our investments, low prevailing market rates and relatively short effective maturities of debt instruments, interest rate risk is mitigated. If market interest rates were to increase immediately and uniformly by 10% from levels at September 30, 2012, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We do not own derivative financial instruments in our investment portfolio. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative, foreign currency or other financial instruments that would require disclosure under this item.

Item 4. Controls and Procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2012. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2012, our disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) occurred during the nine months ended September 30, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

In August 2008, Teva and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed suit against us and Sandoz in the United Stated Federal District Court in the Southern District of New York in response to the filing by Sandoz of the ANDA with a Paragraph IV certification for M356. The suit alleges infringement related to four of the seven Orange Book patents listed for Copaxone. We and Sandoz asserted defenses of non-infringement, invalidity and unenforceability and filed counterclaims for declaratory judgments to have all seven of the Orange Book patents as well as two additional patents in the same patent family adjudicated in the present lawsuit. Another company, Mylan Inc., or Mylan, also has an ANDA for generic Copaxone under FDA review. In October 2009, Teva sued Mylan for patent infringement related to the Orange Book patents listed for Copaxone, and in October 2010, the court consolidated the Mylan case with the case against us and Sandoz. A trial on the issue of inequitable conduct occurred in July 2011 and the trial on the remaining issues occurred in September 2011 in the consolidated case. In June 2012, the Court issued its opinion and found all of the claims in the patents to be valid, enforceable and infringed. In July 2012, the Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing all of the patents in the suit. The Orange Book patents and one non-Orange book patent expire in May 2014 and one non-Orange Book patent expires in September 2015. In addition, the permanent injunction further restricts the FDA, pursuant to 35 U.S.C. section 271(e)(4)(A), from making the effective date of any final approval of the Sandoz or Mylan ANDA prior to the expiration of the Orange Book patents. In July 2012, we appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in October 2012, we and Mylan filed appellate briefs.

In December 2009, in a separate action in the same court, Teva sued Sandoz, Novartis AG and us for patent infringement related to certain other non-Orange Book patents after Teva's motion to add those patents to the ongoing Paragraph IV litigation was denied. In January 2010, we and Sandoz filed a motion to dismiss this second suit on several grounds, including the failure of Teva to state an actionable legal claim and lack of subject matter jurisdiction. The motion is pending. We intend to defend this suit.

If the decision in the first suit is not reversed on appeal, or we are not successful in the second suit, the final approval and launch of M356 could be significantly delayed until expiration of the relevant patent rights which could impair our ability to commercialize M356 and our business could be materially harmed. Litigation involves many risks and uncertainties, and there is no assurance that Novartis AG, Sandoz or we will prevail in either lawsuit.

In September 2011, we and Sandoz sued Amphastar, Watson and International Medical Systems, Ltd. (a wholly owned subsidiary of Amphastar) in the United States District Court for the District of Massachusetts for infringement of two of our patents. Also in September, 2011, we filed a request for a temporary restraining order and preliminary injunction to prevent Amphastar, Watson and International Medical Systems, Ltd. from selling their enoxaparin sodium product in the United States. In October 2011, the court granted our motion for a preliminary injunction and entered an order enjoining Amphastar, Watson and International Medical Systems, Ltd. from advertising, offering for sale or selling their enoxaparin sodium product in the United States until the conclusion of a trial on the merits and required us and Sandoz to post a security bond of $100 million in connection with the litigation. Amphastar, Watson and International Medical Systems, Ltd. appealed the decision to the CAFC, and in January 2012, the CAFC stayed the preliminary injunction, pending a decision on appeal. In June 2012, Amphastar filed a motion to increase the amount of the security bond, which we and Sandoz have opposed. In August 2012, the CAFC issued a written opinion vacating the preliminary injunction and remanding the case to the District Court. In September 2012, we filed a petition with the CAFC for rehearing by the full court *en banc*. Proceedings in the District Court have been stayed pending the outcome of the appellate proceedings.

In December 2010, we sued Teva in the United States District Court for the District of Massachusetts for infringement of two of our patents. Proceedings in this case have been stayed pending the outcome of the appellate proceedings in the Amphastar case.

While we intend to vigorously prosecute this action against Watson and Amphastar, and we believe that we can ultimately prove our case in court, this suit could last a number of years. As a result, potential recovery of lost profits and damages could await a final judgment after an appeal of a District Court decision. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz will prevail in this patent enforcement suit.

Item 1A. Risk Factors

Investing in our stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to other information included or incorporated by reference in this Quarterly Report on Form 10-Q before purchasing our stock. If any of the following risks actually occur, our business, financial condition or results of operations would likely suffer.

Risks Relating to Our Business

We have incurred a cumulative loss since inception. If we do not generate significant revenue, we may not return to profitability.

We have incurred significant losses since our inception in May 2001. At September 30, 2012, our accumulated deficit was $144.4 million. We may incur annual operating losses over the next several years as we expand our drug commercialization, development and discovery efforts. In addition, we must successfully develop and obtain regulatory approval for our other drug candidates, and effectively manufacture, market and sell any drugs we successfully develop. Accordingly, we may not generate significant revenue in the longer term and, even if we do generate significant revenue, we may never achieve long term-profitability.

To be profitable, we and our collaborative partners must succeed in developing and commercializing drugs with significant market potential. This will require us and our collaborative partners to be successful in a range of challenging activities: developing product candidates; obtaining regulatory approval for product candidates through either existing or new regulatory approval pathways; clearing allegedly infringing patent rights; enforcing our patent rights; and manufacturing, distributing, marketing and selling products. Our profitability will also be dependent on the entry of competitive products and, if so, whether the entry is before or after the launch of our products. We may never succeed in these activities and may never generate revenues that are significant.

Our current revenue is dependent on the continued successful manufacture and commercialization of enoxaparin sodium injection.

Our near-term ability to generate revenue, in large part, depends on the continued successful commercialization of enoxaparin sodium injection. This further depends, in large part, on Sandoz's continued success in manufacturing and commercializing the product, maintaining market share and competing with Lovenox brand competition as well as other generic competition.

Under the 2003 Sandoz Collaboration, rather than paying us a profit share of 45% of contractual profits, Sandoz is now paying us a royalty on net sales. In each product year, which begins July 1, for net sales up to a pre-defined sales threshold the royalty is payable at a 10% rate, and for net sales above the sales threshold the royalty rate increases to 12%. The change in Sandoz contractual payment obligations has caused and will continue to cause our revenue from enoxaparin sodium injection to be significantly reduced compared to 2011. In addition, Sandoz is facing increasing competition and pricing pressure from currently-approved generic competitors, which may impact Sandoz net sales of enoxaparin, which will therefore impact our revenue. Furthermore, other competitors may in the future receive approval to market generic enoxaparin products which may further impact revenue to us.

Under these circumstances, the resulting market price for our enoxaparin sodium injection product has decreased and may decrease further, and we have lost market share and may continue to lose significant market share for enoxaparin sodium injection. All of this may further impact our revenue from enoxaparin sodium injection and, as a result, our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer.

If our patent litigation against Amphastar or Teva related to enoxaparin sodium injection is not successful, we may be liable for damages. In addition, third parties may be able to commercialize a generic Lovenox product without risk of patent infringement damages, and our business may be materially harmed.

If we are not successful in the patent litigation against Amphastar and Watson and do not succeed in obtaining injunctive relief or damages, the reduction in our revenue stream will be permanent and our ability to fund future discovery and development programs may suffer. Furthermore, in the event that we are not successful in appealing the CAFC decision and we lose the case in the District Court, and Amphastar and Watson are able to prove they suffered damages as a result of the preliminary injunction having been in effect, then we could be liable for such damages for up to $35 million of the security bond. This amount may be increased if Amphastar and Watson are successful in their motion to increase the amount of the security bond.

Furthermore, if we are not successful in the patent case against Teva and do not succeed in obtaining injunctive relief, or damages for our lost profits due to infringing sales, and if Teva receives marketing approval, it will be able to commercialize a generic Lovenox. Under these circumstances, the resulting market price for our enoxaparin sodium injection product may be lower and we may lose significant market share for enoxaparin sodium injection. Consequently, our revenue would be reduced and our business, including our near-term financial results and our ability to fund future discovery and development programs, may suffer.

As a result of the District Court ruling in the ongoing patent litigation with Teva, absent a Court of Appeals decision in our favor, we may not be able to launch M356, if approved by the FDA, until September 2015. If we are not successful in commercializing M356 or are significantly delayed in doing so, our business may be materially harmed.

In July 2012, the District Court issued a final order and permanent injunction prohibiting Sandoz and Mylan from infringing the Orange Book patents and one non-Orange Book patent until their expiration. The Orange Book patents expire in May 2014 and the non-Orange Book patent expires in September 2015. In addition, the permanent injunction further restricts the FDA from making the effective date of any final approval of the Sandoz or Mylan ANDA prior to the expiration of the Orange Book patents. We filed a notice of appeal in July 2012 of the decision to the Court of Appeals for the Federal Circuit.

We and Sandoz intend to appeal this decision and defend the other Copaxone-related litigation. However, if the decision is not reversed on appeal, then the final approval and launch of M356 will be significantly delayed until expiration of the relevant patent rights, which could impair our ability to commercialize M356 and our business could be materially harmed.

If efforts by manufacturers of branded products to delay or limit the use of generics or FOBs are successful, our sales of generic and FOB products may suffer.

Many manufacturers of branded products have increasingly used legislative, regulatory and other means to delay regulatory approval and competition from manufacturers of generic drugs and could be expected to use similar tactics to delay competition from FOBs. These efforts have included:

- settling patent lawsuits with generic companies, resulting in such patents remaining an obstacle for generic approval by others;
- settling paragraph IV patent litigation with generic companies to prevent the expiration of the 180-day generic marketing exclusivity period or to delay the triggering of such exclusivity period;
- submitting Citizen Petitions to request the FDA Commissioner to take administrative action with respect to prospective and submitted generic drug applications;
- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of generic drug applications;
- conducting medical education with physicians, payors and regulators that claim that generic products are too complex for generic approval;
- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug standards;
- pursuing new patents for existing products or processes which could extend patent protection for a number of years or otherwise delay the launch of generic drugs; and
- attaching special patent extension amendments to unrelated federal legislation.

The FDA's practice is to rule within 180 days on Citizen Petitions that seek to prevent approval of an ANDA if the petition was filed after the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA. If, at the end of the 180-day period, the ANDA is not ready for approval or rejection, then the FDA has typically denied and dismissed the petition without acting on the petition. Teva Neuroscience, Inc. has filed several Citizen Petitions regarding M356, all of which have been denied and dismissed. However, Teva may seek to file future petitions and may also seek reversal of the denial of a Citizen Petition in federal court. Other third parties may also file Citizen Petitions requesting that the FDA adopt specific approval standards for generic products. If the FDA grants future Citizen Petitions, we and Sandoz may be delayed in obtaining, or potentially unable to obtain, approval of the ANDA for M356 which would materially harm our business.

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

If other generic versions of our product candidates, including M356, are approved and successfully commercialized, our business would suffer.

We expect that certain of our product candidates may face intense and increasing competition from other manufacturers of generic and/or branded products. For example, in September 2009, Mylan announced that the FDA had accepted for filing its ANDA for generic Copaxone and in 2011 Synthon announced that it submitted an ANDA to the FDA for a generic Copaxone. Furthermore, as patents for branded products and related exclusivity periods expire, manufacturers of generic products may receive regulatory approval for generic equivalents and may be able to achieve significant market penetration. As this happens, or as branded manufacturers launch authorized generic versions of such products, market share, revenues and gross profit typically decline, in some cases, dramatically. If any of our generic product offerings, including M356, enter markets with a number of competitors, we may not achieve significant market share, revenues or gross profit. In addition, as other generic products are introduced to the markets in which we participate, the market share, revenues and gross profit of our generic products could decline.

If the market for a reference brand product, including Lovenox or Copaxone, significantly declines, sales or potential sales of our generic product and generic or biosimilar product candidates may suffer and our business would be materially impacted.

Competition in the biotechnology industry is intense. Brand name products face competition on numerous fronts as technological advances are made or new products are introduced. As new products are approved that compete with the reference brand product to our generic product and generic or biosimilar product candidates, including Lovenox or Copaxone, sales of the reference brand products may be significantly and adversely impacted and may render the reference brand product obsolete. In addition, brand companies may pursue life cycle management strategies that also impact our generic products.

For example, we anticipate current injectable treatments commonly used to treat multiple sclerosis (MS), including Copaxone, to experience competition from a number of novel drug products. Novartis' Gilenya (fingolimod) and Sanofi's Aubagio (teriflunomide) are recent entrants in the MS marketplace. Both agents are once-daily oral formulations and may be considered to be a more convenient form of administration than currently available injectable treatments, including Copaxone. Biogen Idec's BG-12, Sanofi's alemtuzumab and Teva's laquinimod are emerging novel products that are projected to launch in the near future. These may offer a more convenient form of administration than Copaxone. In addition, in anticipation of increasing competition, Teva, the brand manufacturer of Copaxone, is also pursuing development of a 3-time weekly subcutaneous to alleviate the injection burden associated with the once-daily formulation of Copaxone. If approved, this formulation would compete with our generic version of once-daily injectable Copaxone.

If the market for the reference brand product is impacted, we in turn may lose significant market share or market potential for our generic or biosimilar products and product candidates, and the value for our generic or biosimilar pipeline could be negatively impacted. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

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

We and our collaborative partners and vendors obtain certain raw materials, including UFH, from suppliers who in turn source the materials from other countries, including four suppliers in China. In 2008, due to the occurrence of adverse events associated with the use of UFH, there were global recalls of UFH products, including in the United States, putting our supply chain at risk. Based on investigation by the FDA into those adverse events, the FDA identified a heparin-like contaminant in the implicated UFH products and recommended that manufacturers and suppliers of UFH use additional tests to screen their UFH active pharmaceutical ingredient. We and our collaborative partner worked with the appropriate regulatory authorities to document and to demonstrate that our testing standards meet or exceed all requirements for testing and screening the supply of UFH active pharmaceutical ingredient. The FDA and other authorities have also placed restrictions on the import of some raw materials from China, and may in the future place additional restrictions and testing requirements on the use of raw materials, including UFH, in products intended for sale in the United States. As a result, the raw materials, including UFH, used in our products may become difficult to obtain, significantly increase in cost, or become unavailable to us. If any of these events occur, we and our collaborative partners may be unable to produce our products in sufficient quantities to meet the requirements for the commercial launch or demand for the product, which would have a material adverse impact on our business.

If we or our collaborative partners and other third parties are unable to satisfy FDA quality standards and related regulatory requirements, experience manufacturing difficulties or are unable to manufacture sufficient quantities of our products or product candidates, our development and commercialization efforts may be materially harmed.

We have limited personnel with experience in, and we do not own facilities for, manufacturing any products. We depend upon our collaborative partners and other third parties to provide raw materials meeting FDA quality standards and related regulatory requirements, manufacture the drug substance, produce the final drug product and provide certain analytical services with respect to our products and product candidates, including enoxaparin sodium injection. We, our collaborative partners or our third-party contractors may have difficulty meeting FDA manufacturing requirements, including, but not limited to, reproducibility, validation and scale-up, and continued compliance with current good manufacturing practices requirements. In addition, events such as the contamination of UFH may have an adverse impact on the supply of starting or raw materials for some of our products and product candidates, and we, our collaborative partners or our third-party contractors may have difficulty producing products in the quantities necessary to meet FDA requirements or meet anticipated market demand. If we, our collaborative partners or our third-party manufacturers or suppliers are unable to satisfy the FDA manufacturing requirements for our products and product candidates, or are unable to produce our products in sufficient quantities to meet the requirements for the launch of the product or to meet market demand, our revenue and gross margins could be adversely affected, and could have a material adverse impact on our business.

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

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

Many of our competitors have:

- significantly greater financial, technical and human resources than we have at every stage of the discovery, development, manufacturing and commercialization process;
- more extensive experience in commercializing generic drugs, conducting preclinical studies, conducting clinical trials, obtaining regulatory approvals, challenging patents and 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/or 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;
- with regard to our generic or biosimilar product candidates, the differential availability of clinical data and experience;
- the timing and scope of regulatory approvals for these products and regulatory opposition to any product approvals;
- the availability and cost of manufacturing, marketing, distribution and sales capabilities;
- the effectiveness of our marketing, distribution and sales capabilities;
- the price of our products;
- the availability and amount of third-party reimbursement for our products; and
- the strength of our patent position.

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

If we or our collaborators are unable to establish and maintain key customer distribution arrangements, sales of our products, and therefore revenue, would decline.

Generic pharmaceutical products are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. As enoxaparin sodium injection is primarily a hospital-based product, a large percentage of the revenue for enoxaparin sodium injection is derived 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 or our collaborators have established contracts may also have relationships with our competitors and may decide to contract for or otherwise prefer products other than ours, limiting access of enoxaparin sodium injection to certain hospital segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by our customers, including the GPOs, wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our products. We anticipate that M356 will be primarily distributed through retail channels and mail order services. If we or our collaborators are unable to establish and maintain distribution arrangements with all of these customers, sales of our products, our revenue and our profits would suffer.

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

Even if our product candidates are successfully developed and approved for marketing, our success and growth will also depend upon the acceptance of our products by patients, physicians and third-party payors. Acceptance of our products 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 product 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;
- physician confidence in the safety and efficacy of complex generic products;
- the success and extent of our physician education and marketing programs;
- the clinical, medical affairs, sales, distribution and marketing efforts of competitors; and
- the availability and amount of government and third-party payor reimbursement.

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

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

As of September 30, 2012, we had cash, cash equivalents and marketable securities totaling $361.8 million and accounts receivable of approximately $5.0 million. For the nine months ended September 30, 2012, we had a net loss of $41.0 million and cash provided by operating activities of $28.2 million. We will continue to require substantial funds to conduct research and development, process development, manufacturing, preclinical testing and clinical trials of our product candidates, as well as funds necessary to manufacture and market products that are approved for commercial sale. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and commercialize our products under development. Our future capital requirements may vary depending on the following:

- the rate of sales of enoxaparin sodium injection;
- a final decision, after appeal, is issued in favor of Teva in its patent infringement litigation matters against us;
- the advancement of our product candidates and other development programs, including the timing and costs of obtaining regulatory approvals;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation, including with Amphastar and Watson relating to enoxaparin, 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 third parties should we be unsuccessful in such litigation;
- the ability to enter into strategic collaborations;
- 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 expect to finance our current programs and planned operating requirements principally through our current cash, cash equivalents and marketable securities. We believe that these funds will be sufficient to meet our operating requirements through at least 2015. We may seek additional funding in the future and intend to do so through collaborative arrangements and public or private equity and debt financings or from other sources. Any additional capital raised through the sale of equity may dilute existing investors' percentage ownership of our common stock. Capital raised through debt financing would require us to make periodic interest payments and may impose potentially restrictive covenants on the conduct of our business. Additional funds may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own.

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

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

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

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

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

As we advance our product candidates through the development process, we will need to expand our development, regulatory, manufacturing, quality, distribution, 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. For example, some jurisdictions, such as the District of Columbia, have imposed licensing requirements for sales representatives. In addition, the District of Columbia and the Commonwealth of Massachusetts, as well as the Federal government by way of the Sunshine Act provisions of the Patient Protection and Affordable Care Act of 2010, have established reporting requirements that would require public reporting of consulting and research fees to health care professionals. Because the reporting requirements vary in each jurisdiction, compliance will be complex and expensive and may create barriers to entering the commercialization phase. The need to build new systems as part of our 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. Such requirements may also impact our opportunities to collaborate with physicians at academic research centers as new restrictions on academic-industry relationships are put in place. In the past, collaborations between academia and industry have led to important new innovations, but the new laws may have an effect on these activities. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability.

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

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

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

- difficulty integrating the operations and personnel of the acquired business, and difficulty retaining the key personnel of the acquired business;
- difficulty incorporating the acquired technologies;
- difficulties or failures with the performance of the acquired technologies or drug products;
- we may face product liability risks associated with the sale of the acquired company's products;
- disruption or diversion of management's attention by transition or integration issues and the complexity of managing diverse locations;
- difficulty maintaining uniform standards, internal controls, procedures and policies;
- the acquisition may result in litigation from terminated employees or third parties; and
- we may experience significant problems or liabilities associated with product quality, technology and legal contingencies.

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

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

Risks Relating to Development and Regulatory Approval

If we are not able to obtain regulatory approval for commercial sale of our generic product candidate, M356, as a therapeutic equivalent to Copaxone, 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 M356. We will be required to demonstrate to the satisfaction of the FDA, among other things, that M356:

- contains the same active ingredients as Copaxone;
- is of the same dosage form, strength and route of administration as Copaxone, and has the same labeling as the approved labeling for Copaxone, with certain exceptions; and
- meets compendial or other applicable standards for strength, quality, purity and identity, including potency.

In addition, approval of a generic product generally requires demonstrating that the generic drug is bioequivalent to the reference listed drug upon which it is based, meaning that there are no significant differences with respect to the rate and extent to which the active ingredients are absorbed and become available at the site of drug action. However, the FDA may or may not waive the requirements for certain bioequivalence data (including clinical data) for certain drug products, including injectable solutions that have been shown to contain the same active and inactive ingredients in the same concentration as the reference listed drug.

Determination of therapeutic equivalence of M356 to Copaxone will be based, in part, on our demonstration of the chemical equivalence of our versions to their respective reference listed drugs. The FDA may not agree that we have adequately characterized M356 or that M356 and Copaxone are chemical equivalents. In that case, the FDA may require additional information, including preclinical or clinical test results, to determine therapeutic equivalence or to confirm that any inactive ingredients or impurities do not compromise the product's safety and efficacy. Provision of sufficient information for approval may be difficult, expensive and lengthy. We cannot predict whether M356 will receive FDA approval as therapeutically equivalent to Copaxone.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of Copaxone, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of M356 could be delayed or prevented or become more expensive. In addition, FDA is currently prohibited from granting final marketing approval until May 2014 as a result of ongoing patent litigation. Delays in any part of the process or our inability to obtain regulatory approval for M356 could adversely affect our operating results by restricting or significantly delaying our introduction of M356.

Although health care reform legislation that establishes a regulatory pathway for the approval by the FDA of FOBs has been enacted, the standards for determining sameness or similarity for FOBs are only just being implemented by the FDA. Therefore, substantial uncertainty remains about the potential value our proprietary technology platform can offer to FOB development programs.

The regulatory climate in the United States for follow-on versions of biologic and complex protein products remains uncertain, even following the recent enactment of legislation establishing a regulatory pathway for the approval of FOBs. The new pathway contemplates approval of two categories of follow-on biologic products: (1) biosimilar products, which are highly similar to the existing brand product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences from the brand product and (2) interchangeable products, which in addition to being biosimilar can be expected to produce the same clinical result in any given patient without an increase in risk due to switching from the brand product. Only interchangeable biosimilar products would be considered interchangeable at the retail pharmacy level. The new legislation authorizes but does not require the FDA to establish standards or criteria for determining biosimilarity and interchangeability, and also authorizes the FDA to use its discretion to determine the nature and extent of product characterization, nonclinical testing and clinical testing on a product-by-product basis. Our competitive advantage in this area will depend on our success in demonstrating to the FDA that our analytics, biocharacterization and protein engineering platform technology provides a level of scientific assurance that facilitates determinations of interchangeability, reduces the need for expensive clinical or other testing, and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a brand product. Our ability to succeed will depend in part on our ability to invest in new programs and develop data in a timeframe that enables the FDA to consider our approach as the agency begins to implement the new law. In addition, the FDA will likely require significant new resources and expertise to review biosimilar applications, and the timeliness of the review and approval of our future applications could be adversely affected if there were a decline or even limited growth in FDA funding.

The new regulatory pathway also creates a number of additional obstacles to the approval and launch of biosimilar and interchangeable products, including:

- an obligation of the applicant to share, in confidence, the information in its abbreviated pathway application with the brand company's and patent owner's counsel as a condition to using the new patent clearance process;
- the inclusion of multiple potential patent rights in the patent clearance process; and
- a grant to each brand company of 12 years of marketing exclusivity following the brand approval.

Furthermore, the new regulatory pathway creates the risk that the brand company, during its 12-year marketing exclusivity period, will develop and replace its product with a non-substitutable or modified product that may also qualify for an additional 12-year marketing exclusivity period, reducing the opportunity for substitution at the retail pharmacy level for an interchangeable FOB. Finally, the new legislation also creates the risk that, as brand and FOB companies gain experience with the new regulatory pathway, subsequent FDA determinations or court rulings could create additional areas for potential disputes and resulting delays in FOB approval.

In addition, there is reconsideration and legislative debate that could lead to the repeal or amendment of the new healthcare legislation. If the legislation is significantly amended or is repealed with respect to the biosimilar approval pathway, our opportunity to develop biosimilars (including interchangeable biologics) could be materially impaired and our business could be materially and adversely affected.

Even if we are able to obtain regulatory approval for our generic and interchangeable biologic product candidates as therapeutically equivalent or interchangeable, state pharmacy boards or agencies may conclude that our products are not substitutable at the pharmacy level for the reference listed drug. If our generic or interchangeable biologic products are not substitutable at the pharmacy level for their reference listed drugs, this could materially reduce sales of our products and our business would suffer.

Although the FDA may determine that a generic product is therapeutically equivalent to a brand product and provide it with an "A" rating in the FDA's Orange Book, this designation is not binding on state pharmacy boards or agencies. As a result, in states that do not deem our product candidates therapeutically equivalent, physicians will be required to specifically prescribe a generic product alternative rather than have a routine substitution at the pharmacy level for the prescribed brand product. Should this occur with respect to one of our generic product candidates, it could materially reduce sales in those states which would substantially harm our business.

While a designation of interchangeability is a finding by the FDA that a biosimilar can be substituted at the pharmacy without physician intervention or prescription, brand pharmaceutical companies are lobbying state legislatures to enact physician prescription requirements, or in the absence of a prescription, physician and patient notification requirements, special labeling requirements and alternative naming requirements

which if enacted could create barriers to substitution and adoption rates of interchangeable biologics as well as biosimilars. Should this occur with respect to one of our FOB product candidates, it could materially reduce sales in those states which would substantially harm our business.

If our preclinical studies and clinical trials for our development candidates, including M402, 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 drug candidates, we are required to demonstrate through preclinical studies and clinical trials that our drug development candidates are safe and effective. Preclinical studies and clinical trials of new development candidates are lengthy and expensive and the historical failure rate for development candidates is high.

A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize M402 or our other drug candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our preclinical studies or clinical trials may produce negative or inconclusive results, and we may be required to conduct additional preclinical studies or clinical trials or we may abandon projects that we previously expected to be promising;
- enrollment in our clinical trials may be slower than we anticipate, resulting in significant delays, and participants may drop out of our clinical trials at a higher rate than we anticipate;
- we might have to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or if, in their opinion, participants are being exposed to unacceptable health risks;
- the cost of our clinical trials may be greater than we anticipate; and
- the effects of our drug candidates may not be the desired effects or may include undesirable side effects or our product candidates may have other unexpected characteristics.

The results from preclinical studies of a development candidate may not predict the results that will be obtained in human clinical trials. If we are required by regulatory authorities to conduct additional clinical trials or other testing of M402 or our other product candidates that we did not anticipate, if we are unable to successfully complete our clinical trials or other tests, or if the results of these trials are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for our drug candidates or we may not be able to obtain marketing approval at all. Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or potential products. If any of these events occur, our business will be materially harmed.

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

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

Even if we obtain regulatory approvals, our marketed products 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 products and our business would be seriously harmed.

Even after approval, any drugs or biological products we develop will be subject to ongoing regulatory review, including the review of clinical results which are reported after our products are made commercially available. Any regulatory approvals that we obtain for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of

approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, the manufacturer and manufacturing facilities we use to produce any of our product candidates will be subject to periodic review and inspection by the FDA, or foreign equivalent, and other regulatory agencies. We will be required to report any serious and unexpected adverse experiences and certain quality problems with our products and make other periodic reports to the FDA. The discovery of any new or previously unknown problems with the product, manufacturer or facility may result in restrictions on the product or manufacturer or facility, including withdrawal of the product 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 FDA regulatory requirements, we may be subject to fines, warning letters, civil penalties, refusal by the FDA to approve pending applications or supplements, suspension or withdrawal of regulatory approvals, product recalls and seizures, injunctions, operating restrictions, refusal to permit the import or export of products, and/or criminal prosecutions and penalties.

Similarly, our commercial activities will be subject to comprehensive compliance obligations under state and federal reimbursement, sunshine act, anti-kickback and government pricing regulations. If we make false price reports, fail to implement adequate compliance controls or our employees violate the laws and regulations governing relationships with health care providers, we could also be subject to substantial fines and penalties, criminal prosecution and debarment from participation in the Medicare, Medicaid, or other government reimbursement programs.

In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

If third-party payors do not adequately reimburse customers for any of our approved products, they might not be purchased or used, and our revenue and profits will not develop or increase.

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

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

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

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

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

Federal legislation will increase the pressure to reduce prices of pharmaceutical products paid for by Medicare or may otherwise seek to limit healthcare costs, either of which could adversely affect our revenue, if any.

The Medicare 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.

Furthermore, health care reform legislation was enacted in 2010 that could significantly change the United States health care system and the reimbursement of products. A primary goal of the law is to reduce or limit the growth of health care costs, which could change the market for pharmaceuticals and biological products.

The law contains provisions that will affect companies in the pharmaceutical industry and other healthcare-related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include an increase to the mandatory rebates for drugs sold into the Medicaid program, an extension of the rebate requirement to drugs used in risk-based Medicaid managed care plans, an extension of mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities, and discounts and fees applicable to brand-name drugs. Although many of these provisions may not apply directly to us, they may change business practices in our industry and, assuming our products are approved for commercial sale, such changes could adversely impact our profitability.

Additionally, the new law establishes an abbreviated regulatory pathway for the approval of FOBs and provides that brand biologic products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. By creating a new approval pathway for FOBs and adjusting reimbursement for FOBs, the new law could promote the development and commercialization of FOBs. However, given the uncertainty of how the law will be interpreted and implemented, the impact of the law on our strategy for follow-on as well as novel biologics remains uncertain. Other provisions in the law, such as the comparative effectiveness provisions, may ultimately impact positively or negatively both brand and FOB products alike depending on an applicant's clinical data, effectiveness and cost profile. If a brand product cannot be shown to provide a benefit over other therapies, then it might receive reduced coverage and reimbursement. While this might increase market share for FOBs based on cost savings, it could also have the effect of reducing FOB market share.

The financial impact of this United States health care reform legislation over the next few years will depend on a number of factors, including but not limited to the issuance of implementation regulations and guidance and changes in sales volumes for products eligible for the new system of rebates, discounts and fees. Assuming our products are approved for commercial sale, the new legislation could also have a positive impact on us by increasing the aggregate number of persons with health care coverage in the United States and expanding the market for our products, but such increases, if any, are unlikely to be realized until approximately 2014 at the earliest.

The full effects of the United States health care reform legislation cannot be known until the new law is implemented through regulations or guidance issued by the CMS and other federal and state health care agencies. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability. In addition, litigation may prevent some or all of the legislation from taking effect. Consequently, there is uncertainty regarding implementation of the new legislation.

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

In some foreign countries, particularly the countries of the European Union, the pricing and/or reimbursement of prescription pharmaceuticals are 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, 2011, 2010 and 2009, we spent approximately $52,000, $57,000 and

$125,000, respectively, in order to comply with environmental and waste disposal regulations. 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. Insurance may not provide adequate coverage against potential liabilities and 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.

The FDA has reported that it has a substantial backlog of ANDA filings that have resulted in significant delays in review and approval of applications. As a result, the review and potential approval of our application for M356 may be significantly delayed.

The FDA has reported that it has a substantial backlog of ANDA filings that have resulted in significant delays in the review and approval of ANDAs and amendments or supplements due to insufficient staffing and resources. Resource constraints have also resulted in significant delays in conducting ANDA-related pre-approval inspections. Enactment of user fee legislation in 2012 is expected to fund additional resources and the new legislation implements goals and metrics for application review to begin to address this backlog and the delays. Still, when an ANDA review requires coordination with the new drug offices of the FDA, the FDA is obligated to give priority to NDA and BLA applications that are subject to statutory review time periods as well. Until such time as resources are actually increased by the FDA, our applications and supplements may be subject to significant delays during their review cycles. In addition, if a user fee statute is enacted, we may become liable for fees that could be material to our earnings.

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. 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.

Assuming the other requirements for patentability are met, currently, in the United States, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. In March 2013, the United States will transition to a first inventor to file system in which, assuming the other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter parties* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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.

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 U.S. Patent and Trademark Office and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries.

Although we are aggressively pursuing patent applications on our innovative approaches to characterization and manufacture of complex generics, FOBs and new drugs, there is presently uncertainty regarding the scope of the safe harbor from a patent infringement enforcement under federal patent law, 35 USC section 271(e)(1). This uncertainty may impair our ability to enforce certain of our patent rights and reduce the likelihood of enforcing certain of our patent rights to protect our innovations and our products. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims allowed in any patents issued to us or to others.

The allowance of broader claims may increase the incidence and cost of patent interference proceedings and/or opposition proceedings, and the risk of infringement litigation. On the other hand, the allowance of narrower claims may limit the value of our proprietary rights. Our issued

patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage. Moreover, once they have issued, our patents and any patent for which we have licensed or may license rights may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited, other companies will be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

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

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

The issuance of our own patents does not guarantee that we have the right to practice the patented inventions. 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.

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

Any legal action against us or our collaborators claiming damages and seeking to enjoin any activities, including commercial activities relating to the affected products, and processes could, in addition to subjecting us to potential liability for damages, require us or our collaborators to obtain a license in order to continue to manufacture or market the affected products and processes. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, some licenses may be non-exclusive, and therefore, our competitors may have access to the same technology licensed to us.

If we fail to obtain a required license or are unable to design around a patent, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

If we become involved in patent litigation or other proceedings to determine or enforce our intellectual property rights, we could incur substantial costs which could adversely affect our business.

We may need to resort to litigation to enforce a patent issued to us or to determine the scope and validity of a third-party patent or other proprietary rights such as trade secrets in jurisdictions where we intend to market our products, including the United States, the European Union, and many other foreign jurisdictions. The cost to us of any litigation or other proceeding relating to determining the validity of intellectual property rights, even if resolved in our favor, could be substantial and could divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they may have substantially greater resources. Moreover, the failure to obtain a favorable outcome in any litigation in a jurisdiction where there is a claim of patent infringement could significantly delay the marketing of our products in that particular jurisdiction. Counterclaims for damages and other relief may be triggered by such enforcement actions. The costs, uncertainties and counterclaims 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 diligence, development, royalty and other obligations on us. If we breach our obligations with regard to our exclusive in-licenses, they could be converted to non-exclusive licenses or the agreements could be terminated, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology.

Risks Relating to Our Dependence on Third Parties

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

2003 Sandoz Collaboration

Either we or Sandoz may terminate the 2003 Sandoz Collaboration for material uncured breaches or certain events of bankruptcy or insolvency by the other party. Sandoz may also terminate the 2003 Sandoz Collaboration if the enoxaparin sodium injection product or the market lacks commercial viability, if new laws or regulations are passed or court decisions rendered that substantially diminish our legal avenues for commercialization of enoxaparin sodium injection, or, in multiple cases, if certain costs exceed mutually agreed upon limits. If the 2003 Sandoz Collaboration is terminated other than due to our uncured breach or bankruptcy, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize enoxaparin sodium injection in the United States. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from commercializing enoxaparin sodium injection. If Sandoz terminates the 2003 Sandoz Collaboration due to our uncured breach or bankruptcy, Sandoz would retain the exclusive right to commercialize enoxaparin sodium injection in the United States. In that event, we would no longer have any influence over the commercialization strategy of enoxaparin sodium injection in the United States. In addition, Sandoz would retain its rights of first negotiation with respect to certain of our other products in certain circumstances and its rights of first refusal outside of the United States and the European Union. Accordingly, if Sandoz terminates the 2003 Sandoz Collaboration, we may decide to discontinue the enoxaparin sodium injection project, or our revenue may be reduced, any one of which could have a material adverse effect on our business.

2006 Sandoz Collaboration

Either we or Sandoz may terminate the Second Sandoz Collaboration Agreement for material uncured breaches or certain events of bankruptcy or insolvency by the other party. In addition, either we or Sandoz may terminate some of the products, on a product-by-product basis, if clinical trials are required. For some of the products, for any termination of the Second Sandoz Collaboration Agreement other than a termination by Sandoz due to our uncured breach or bankruptcy, or a termination by us alone due to the need for clinical trials, we will be granted an exclusive license under certain intellectual property of Sandoz to develop and commercialize the particular product. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. For some products, if Sandoz terminates the Second Sandoz Collaboration Agreement due to our uncured breach or bankruptcy, or if there is a termination by us alone due to the need for clinical trials, Sandoz would retain the exclusive right to develop and commercialize the applicable product. In that event, we would no longer have any influence over the development or commercialization strategy of such product. In addition, for other products, if Sandoz terminates due to our uncured breach or bankruptcy, Sandoz retains a right to license certain of our intellectual property without the obligation to make any additional payments for such licenses. For certain products, if the Second Sandoz Collaboration Agreement is terminated other than due to our uncured breach or bankruptcy, neither party will have a license to the other party's intellectual property. In that event, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from completing the development and commercialization of such product. Accordingly, if the Second Sandoz Collaboration Agreement is terminated, our introduction of certain products may be significantly delayed, or our revenue may be significantly reduced either of which could have a material adverse effect on our business.

The Baxter Agreement is important to our business. If we or Baxter fail to adequately perform under the Agreement, or if we or Baxter terminate all or a portion of the Agreement, the development and commercialization of some of our FOB candidates would be delayed or terminated and our business would be adversely affected.

The Baxter Agreement may be terminated:

- by either party for breach by the other party (in whole or on a product by product or country-by-country basis);
- by either party for bankruptcy of the other party;
- by us in the event Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products within a certain time period;
- by Baxter for its convenience (in whole or on a product by product basis);
- by us in the event Baxter does not exercise commercially reasonable efforts to commercialize a product in the United States or other specified countries, provided, that we also have certain rights to directly commercialize such product, as opposed to terminating the Baxter Agreement, in event of such a breach by Baxter; or
- by either party in the event there is a condition constituting force majeure for more than a certain consecutive number of days.

If the Baxter Agreement were terminated by Baxter for convenience or if Baxter elects to terminate the Baxter Agreement with respect to both of the initial two products in the specified time frame or if we terminate the Baxter Agreement for breach by Baxter, while we would have the right to research, develop, manufacture or commercialize the terminated products or license a third party to do so, we would need to expand our internal capabilities or enter into another collaboration, which could cause significant delays that could prevent us from commercializing our FOB

candidates. In addition, we may need to seek additional financing to support the research, development and commercialization of the terminated products or alternatively we may decide to discontinue the terminated products, which could have a material adverse effect on our business. If Baxter terminates the Baxter Agreement due to our uncured breach, Baxter would retain the exclusive right to commercialize the terminated products on a world-wide basis, subject to certain payment obligations to us as outlined in the Agreement. In addition, depending upon the timing of the termination, we would no longer have any influence over or input into the clinical development strategy or/and the commercialization strategy or/and the legal strategy of the products in the territory.

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

We have a limited number of personnel with experience in, and we do not own facilities for, manufacturing 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 product candidates, apply for regulatory approvals and commercialize any products, we or our collaborative partners need to contract for or otherwise arrange for the necessary manufacturing facilities and capabilities. In order to generate revenue from the sales of enoxaparin sodium injection, sufficient quantities of such product must also be produced in order to satisfy demand. If these contract manufacturers are unable to manufacture sufficient quantities of product, comply with regulatory requirements, or breach or terminate their manufacturing arrangements with us, the development and commercialization of the affected products or drug candidates could be delayed, which could have a material adverse effect on our business. In addition, any change in these manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

We have relied upon third parties to produce material for preclinical and clinical studies and may continue to do so in the future. We cannot be certain that we will be able to obtain and/or maintain long-term supply and supply arrangements of those materials on acceptable terms, if at all. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our products or market them.

In addition, the FDA and other regulatory authorities require that our products be manufactured according to current good manufacturing practices, or cGMP, regulations and that proper procedures are implemented to assure the quality of our sourcing of raw materials and the manufacture of our products. Any failure by us, our collaborative partners or our third-party manufacturers to comply with cGMP, and/or our failure to scale-up our manufacturing processes could lead to a delay in, or failure to obtain, regulatory approval. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action, including product recall or seizure, fines, imposition of operating restrictions, total or partial suspension of production or injunctions. To the extent we rely on a third-party manufacturer, the risk of non-compliance with cGMPs may be greater and the ability to effect corrective actions for any such noncompliance may be compromised or delayed.

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

We do not have a sales organization and have no experience as a company in the sale, marketing or 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 or distribution services, we will have less control over sales of our products and our future revenue would depend heavily on the success of the efforts of these third parties.

General Company Related Risks

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; and
- limitations on the removal of directors.

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

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

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

- failure to obtain FDA approval for the M356 ANDA;
- failure of enoxaparin sodium injection to sustain commercial success or to meet expectations of securities analysts;
- failure to obtain clarity from the Court of Appeals for the Federal Circuit or Supreme Court regarding the appropriate scope of the safe harbor provisions from patent infringement;
- other adverse FDA decisions relating to our enoxaparin sodium injection product or M356 program, including an FDA decision to require additional data, including requiring clinical trials, as a condition to M356 ANDA approval;
- litigation involving our company or our general industry or both, including litigation pertaining to the launch of our, our collaborative partners' or our competitors' products;
- a decision in favor of or against Teva or Amphastar and Watson in the current patent litigation matters, or a settlement related to any case;
- announcements by other companies regarding the status of their ANDAs for generic versions of Lovenox or Copaxone;
- FDA approval of other companies' ANDAs for generic versions of Lovenox or Copaxone;
- marketing and/or launch of other companies' generic versions of Lovenox or Copaxone;
- adverse FDA decisions regarding the development requirements for one or our FOB development candidates or failure of our other product applications to meet the requirements for regulatory review and/or approval;
- results or delays in our or our competitors' clinical trials or regulatory filings;
- legislation is enacted that repeals the law enacting the biosimilar regulatory approval pathway or amends the law in a manner that is adverse to our biosimilar development strategy;
- failure to demonstrate therapeutic equivalence, biosimilarity or interchangeability with respect to our technology-enabled generic product candidates or FOBs;
- demonstration of or failure to demonstrate the safety and efficacy for our novel development product candidates;
- our inability to manufacture any products in conformance with cGMP or in sufficient quantities to meet the requirements for the commercial launch of the product or to meet market demand;
- failure of any of our product candidates, if approved, to achieve commercial success;

- the discovery of unexpected or increased incidence in patients' adverse reactions to the use of our products or product candidates or indications of other safety concerns;
- 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 collaborations;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- investors' general perception of our company, our products, the economy and general market conditions;
- rapid or disorderly sales of stock by holders of significant amounts of our stock; or
- significant fluctuations in the price of securities generally or biotech company securities specifically.

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

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

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

Item 6.	Exhibits.
10.1†	Collaboration and License Agreement, dated November 1, 2003, by and among Biochemie West Indies, N.V., Geneva Pharmaceuticals, Inc. and the Registrant
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101+	The following materials from Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at September 30, 2012 and December 31, 2011, (ii) the Condensed Consolidated Statements of Comprehensive (Loss) Income for the three and nine months ended September 30, 2012 and September 30, 2011, (iii) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and September 30, 2011, and (iv) Notes to Unaudited, Condensed Consolidated Financial Statements.

† Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

+In accordance with Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q shall be deemed to be "furnished" and not "filed."

SIGNATURES

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

Momenta Pharmaceuticals, Inc.

Date: November 8, 2012

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

Date: November 8, 2012

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

Exhibit 10.1

EXECUTION COPY

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

COLLABORATION AND LICENSE AGREEMENT

By and Among

Momenta Pharmaceuticals, Inc.

and

Biochemie West Indies, N.V.

and

Geneva Pharmaceuticals, Inc.

November 1, 2003

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

PRIVILEGED AND CONFIDENTIAL

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement ("Agreement") is entered into as of this 1st day of November, 2003 ("Effective Date"), by and between Momenta Pharmaceuticals, Inc., a Delaware corporation ("Momenta") with a principal place of business at 43 Moulton Street, Cambridge, Massachusetts, USA 02138, Biochemie West Indies, N.V., a Netherlands Antilles corporation ("BCWI") with a principal place of business at Pietermaai 6A, Willemstad, Curacao, Netherlands Antilles, and Geneva Pharmaceuticals, Inc., a Colorado corporation ("Sandoz") with a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey USA 08540 (Sandoz, collectively with BCWI, are the "Sandoz Parties", and individually, each is a "Sandoz Party").

RECITALS

WHEREAS, Momenta is a biotechnology company with specific expertise in enoxaparin and the science of complex sugars, polysaccharides, their structures, their sequencing, and their characterization;

WHEREAS, Momenta is the owner and/or licensee of the Momenta Patent Rights and Momenta Know-How, each as defined hereinafter;

WHEREAS, Sandoz has substantial knowledge and expertise in the research, development, manufacture and sale of pharmaceuticals;

WHEREAS, the Sandoz Parties are the owners and/or licensees of the Sandoz Patent Rights and Sandoz Know-How, each as defined hereinafter;

WHEREAS, the Sandoz Parties wish to collaborate with Momenta to develop and commercialize the Product, as defined hereinafter, using the Momenta Patent Rights and Momenta Know-How under the terms and conditions specified herein.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth, the Parties agree as follows:

1. DEFINITIONS

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article 1:

1.1. "Additional Costs Amount". Additional Costs Amount means, initially, Three Million Dollars (U.S.$3,000,000), as may be increased pursuant to Section 11.5.2.

1.2. "Affiliate". Affiliate means any corporation, company, partnership, joint venture and/or firm that controls, is controlled by, or is under common control with a Person. For purposes of this Section 1.2, "control" shall mean (a) in the case of corporate entities, direct or

indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

1.3. "ANDA". ANDA means any of the following: (a) an Abbreviated New Drug Application filed with the FDA or any successor applications or procedures seeking authorization and approval to manufacture, package, ship, and sell a product in the U.S. Territory; (b) any other regulatory filing in the U.S. Territory as mutually agreed by the Parties in the Collaborative Program, including without limitation filings that are similar to filings under clause (a), such as an NDA, supplemental NDA or an application pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act"); and (c) all supplements and amendments that may be filed with respect to the foregoing.

1.4. "ANDA Final Approval". ANDA Final Approval means the granting by the FDA of final Marketing Approval to Sandoz or any of its Affiliates for an ANDA for a Lovenox®-Equivalent Product.

1.5. "Annual Collaboration Plan". Annual Collaboration Plan means the Development, Commercialization and Legal Activities plan for the Collaborative Program to be developed by the Joint Project Team and approved by the Joint Steering Committee for each Contract Year.

1.6. "Aventis". Aventis means (a) Aventis Pharmaceuticals Inc., (b) its Affiliates, (c) the licensees and distributors of Aventis Pharmaceuticals Inc. or its Affiliates for a Lovenox®-Equivalent Product (the Persons described in Sections 1.6(a), (b) and (c), collectively, the "Aventis Persons"), and (d) the successors and assigns of any Aventis Persons with respect to any rights to any Lovenox®-Equivalent Product.

1.7. "Aventis [**]". Aventis [**] means [**] Dollars (U.S.$[**]); provided, however, that, if the Aventis [**] begins on a day after the first day of a Post-Launch Year, the Aventis [**] for the remainder of such Post-Launch Year shall equal the product of (a) the number of days between (and including) the date of such termination of the [**] until the end of such Post-Launch Year, multiplied by (b) the quotient of (i) U.S.$[**] divided by (ii) 365.

1.8. "Business Day". Business Day means any day that is not a Saturday, Sunday or other day on which commercial banks located in the State of New York are authorized or required to be closed.

1.9. "Capped Costs". Capped Costs means collectively Development Costs and Legal Expenses.

1.10. "cGMP". cGMP means current good manufacturing practices as set forth in Title 21, Parts 210 and 211 of the CFR, as established by FDA.

1.11. "Characterize". Characterize and Characterization, with respect to the Product, means chemical and physical characterization of the Product and Lovenox® with sufficient specificity, and documentation thereof as is necessary to establish to the satisfaction of the FDA that the active ingredient of the Product is the same as that of Lovenox®, as required by 21 U.S.C. § 355(j)(2)(A)(ii)(I).

1.12. "Collaboration Know-How". Collaboration Know-How means Sandoz Collaboration Know-How, Joint Collaboration Know-How and Momenta Collaboration Know-How.

1.13. "Collaborative Program". Collaborative Program means the joint initiative to be undertaken by the Parties to Develop and Commercialize, and conduct Legal Activities with respect to, the Product in the U.S. Territory within the Field as described in Articles 5, 6 and 7 and in the Annual Collaboration Plans.

1.14. "Commercial Third Party". Commercial Third Party means a Third Party that is not (a) an academic or non-profit research institution or (b) a hospital; provided that, should any such entity market or manufacture pharmaceutical products, such entity shall be considered a Commercial Third Party.

1.15. "Commercialization," "Commercialize" or "Commercializing". Commercialization, Commercialize or Commercializing means any and all activities directed to commercial manufacturing (including, without limitation, the manufacture of commercial supply for distribution in the U.S. Territory and the manufacture of commercial inventory), marketing, promoting, distributing, importing and/or selling the Product. "Commercialization," "Commercialize" or "Commercializing" does not include Development or Legal Activities.

1.16. "Commercialization Costs". Commercialization Costs means all costs incurred by the Sandoz Parties, Momenta or their Affiliates in connection with Commercializing the Product for sale in the U.S. Territory pursuant to this Agreement, including any capital investment with respect thereto. Commercialization Costs do not include (a) [**] pursuant to the [**] (which shall be the sole responsibility of Momenta), (b) [**], (c) [**], (d) [**] or (e) [**].

1.17. "Commercially Reasonable Efforts". Commercially Reasonable Efforts shall mean, with respect to the efforts to be expended by a Party with respect to any objective, reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances exercising reasonable business judgment, it being understood and agreed that, with respect to the Development or Commercialization of the Product or Legal Activities, such efforts shall be substantially equivalent to those efforts and resources commonly used by such Party for a product owned by it or to which it has rights, which product is at a similar stage in its development or product life and is of similar market potential, taking into account efficacy, safety, approved labeling, the competitiveness of alternative products in the marketplace, the patent and other proprietary position of the Product, the likelihood of regulatory approval given

the regulatory structure involved, the profitability of the Product, alternative products and other relevant factors commonly considered in similar circumstances. It is anticipated that the level of effort will change over time, reflecting changes in the status of the Product.

1.18. "Confidential Information". Confidential Information means all Know-How or other confidential or proprietary information and materials (whether or not patentable) regarding a Party's technology, products or business, which is designated as confidential in writing by the disclosing Party, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such Know-How or other information or material is disclosed by the disclosing Party to the other Party. Notwithstanding the foregoing to the contrary, Know-How or other information or material that is orally or visually disclosed by a Party, or is disclosed in writing without an appropriate letter, stamp or legend, shall constitute Confidential Information of a Party (a) for thirty (30) days after its disclosure and thereafter shall remain Confidential Information if within such 30-day period after such disclosure the disclosing Party delivers to the other Party a written document or documents describing the Know-How or other information or material and referencing the place and date of such oral, visual or written disclosure and the names of the persons to whom such disclosure was made or (b) such information is of the type that is customarily considered to be confidential information by persons engaged in activities that are substantially similar to the activities being engaged in by the Parties pursuant to this Agreement. "Confidential Information" shall not include information: (i) which is or becomes generally available to the public other than as a result of disclosure thereof by the Receiving Party; (ii) which is lawfully received by the Receiving Party on a non-confidential basis from a Third Party that is not itself under any obligation of confidentiality or nondisclosure to the Disclosing Party or any other Person with respect to such information; (iii) which is already known to the Receiving Party at the time of disclosure by the Disclosing Party, or (iv) which can be shown by the Receiving Party to have been independently developed by the Receiving Party without reference to the Disclosing Party's Confidential Information.

1.19. "Contract Year". Contract Year means the period beginning on the Effective Date and ending on December 31, 2003 (the "First Contract Year"), or each succeeding twelve (12) month calendar year period thereafter during the term of the Agreement (referred to as the "Second Contract Year", "Third Contract Year", etc.).

1.20. "Control" or "Controlled". Control or Controlled means with respect to any item of Know-How or any intellectual property right, the possession, whether by ownership or license (other than pursuant to this Agreement), by a Party (and, in the case of Momenta, any of its Affiliates) of the ability to grant to the other Party access and/or a license as provided herein under such item or right without violating the terms of any agreement or arrangement with any Third Party existing before or after the Effective Date.

1.21. "Develop" or "Development". Develop or Development means, with respect to the Product: (a) Characterization of the Product; (b) all activities associated with the filing of an ANDA for the Product as provided for in this Agreement, including, without limitation, preclinical and clinical drug-development activities, such as, but not limited to, toxicology, preclinical and clinical studies; (c) formulation, process development and commercial scale-up (to the commercial batch size agreed upon in the Annual Collaboration Plans which shall be a

batch size that is commercially reasonable given expected production) activities (including test-method development); (d) development of quality assurance/quality control procedures; (e) with respect to the drug substance for the Product, commercial scale validation and commercial scale stability studies; (f) with respect to the drug product form of the Product, commercial scale process validation, commercial scale stability studies, packaging, tooling, package design, packaging validation and labeling preparation; (g) statistical analysis; (h) regulatory affairs (including legal activities with respect thereto); and (i) Product approval and registration activities. "Develop" or "Development" does not include Commercialization or Legal Activities.

1.22. "Development Costs". Development Costs means (a) all costs paid by Sandoz, BCWI or Momenta to Third Parties after the Effective Date in connection with the Development of the Product with respect to the U.S. Territory which are incurred in accordance with the Annual Collaboration Plan, including, without limitation, contractors and licensors in connection with the Development of the Product; (b) those costs incurred by Momenta prior to the Effective Date which are listed on Schedule 1.22 (the "Pre-Existing Costs"); and (c) the costs, calculated pursuant to the definition of Manufacturing Costs, to manufacture any commercial batch(es) of the Product prior to the first batch which is usable as commercial inventory, and (d) any payments for Additional FTEs. Development Costs do not include: (i) [**] for the [**]; (ii) [**] Costs; (iii) [**] the Product; (iv) [**] the Product other than as indicated in clause (c) above; (v) [**] pursuant to the [**]; (vi) [**] Costs; (vii) [**] Expenses; or (viii) [**] Costs.

1.23. "District Court Legal Clearance". District Court Legal Clearance means, with respect to the U.S. Territory, in the event that Orange Book Litigation occurs prior to the granting of ANDA Final Approval for an ANDA filed by Sandoz or any of its Affiliates for the Product, the earlier of (a) a determination, including a summary judgment, from a federal district court (a "District Court") in the Orange Book Litigation (a "District Court Decision") that marketing the Product by or on behalf of Sandoz does not infringe Aventis' Patent Rights, or (b) a determination, from a federal district court, in a patent infringement suit between Aventis and a Third Party, which would permit the marketing of the Product by or on behalf of Sandoz without infringing Aventis' Patent Rights (i) because such Patent Rights have been declared invalid or unenforceable or (ii) if such Patent Rights have not been declared invalid or unenforceable, in Sandoz's reasonable judgment.

1.24. "Excess Costs". Excess Costs means the sum of (a) the amount by which [**], (b) any [**] Costs, and (c) any [**] Costs (notwithstanding any [**] with respect to [**]).

1.25. "Executive Officers". Executive Officers mean (a) the Chief Executive Officer, Chief Financial Officer or Vice President of Business Development of Sandoz (or an officer of Sandoz designated by any of the foregoing officers) (the relevant officer, the "Sandoz Executive Officer"), (b) the Head Caribic of BCWI (or an officer of BCWI designated by such person) (the relevant officer, the "BCWI Executive Officer"), and (c) the Chief Executive Officer of Momenta (or an executive officer of Momenta designated by such officer) (the relevant officer, the "Momenta Executive Officer").

1.26. "FDA". FDA means the United States Food and Drug Administration, or any successor agency thereto.

1.27. "Field". Field means the injectable administration of the Product for any and all medical indications.

1.28. "Final Legal Clearance". Final Legal Clearance means, with respect to the U.S. Territory, (a) the absence of Patent Litigation pursuant to 21 U.S.C. 355(c)(3)(C) or 355(j)(5)(B) with respect to the patents listed in the Orange Book for Lovenox® ("Orange Book Litigation") prior to the granting of ANDA Final Approval for an ANDA filed by Sandoz or any of its Affiliates for the Product, or (b) in the event that Orange Book Litigation occurs prior to the granting of ANDA Final Approval for an ANDA filed by Sandoz or any of its Affiliates for the Product, the earliest of: (i) receipt by Sandoz or any of its Affiliates of a final, unappealable judgment that determines that marketing of the Product by or on behalf of Sandoz does not infringe Aventis' Patent Rights; or (ii) receipt by a Third Party of a final, unappealable judgment in a patent infringement suit between Aventis and such Third Party, which would permit the marketing of the Product by or on behalf of Sandoz without infringing Aventis' Patent Rights either (x) because such Patent Rights have been declared invalid or unenforceable, or (y) if such Patent Rights have not been declared invalid or unenforceable (in Sandoz's reasonable judgment); or (iii) a Settlement.

1.29. "First Commercial Sale". First Commercial Sale means the first commercial sale of the Product in the U.S. Territory as part of a nationwide introduction by Sandoz, its Affiliates and/or distributors. Sales for test marketing, clinical trial purposes or compassionate or similar use shall not give rise to a First Commercial Sale.

1.30. "Fragmin Opportunity". Fragmin Opportunity means the research, development, manufacturing or commercialization of dalteparin as a generic version of Fragmin.

1.31. "FTE". FTE means a full time equivalent person year (consisting of a total of [**] hours per year) of scientific, technical or managerial work on or directly related to the Collaborative Program.

1.32. "FTE Rate". FTE Rate means U.S.$[**] per FTE.

1.33. "Improved Enoxaparin". Improved Enoxaparin means any improved form of enoxaparin which meets the specifications for [**] as of the Effective Date and for which approval by the FDA would require the filing of a New Drug Application under Section [**] of the FD&C Act ([**]).

1.34. "Improvement". Improvement means any enhancement to Sandoz Know-How, Momenta Know-How, Sandoz Collaboration Know-How or Momenta Collaboration Know-How, as the case may be, based on and arising from exposure to such Know-How and made during the conduct of the Collaborative Program, including enhancements made to such Improvements made during the conduct of the Collaborative Program.

1.35. "Joint Collaboration IP". Joint Collaboration IP means Joint Collaboration Know-How and Joint Collaboration Patent Rights.

1.36. "Joint Collaboration Know-How". Joint Collaboration Know-How means all Know-How constituting, based upon or derived from inventions or developments which are conceived and reduced to practice or developed jointly by Sandoz or its Affiliates, on the one hand, and Momenta or its Affiliates, on the other hand, during and in the conduct of the Collaborative Program, excluding those Improvements to Sandoz Know-How, Improvements to Sandoz Collaboration Know-How, Improvements to Momenta Know-How or Improvements to Momenta Collaboration Know-How which are made jointly by Sandoz or its Affiliates, on the one hand, and Momenta or its Affiliates, on the other hand.

1.37. "Joint Collaboration Patent Rights". Joint Collaboration Patent Rights means all Patent Rights throughout the world covering the Joint Collaboration Know-How.

1.38. "Joint Product-Specific Know-How". Joint Product-Specific Know-How means all Joint Collaboration Know-How which solely relates to the Product and does not relate, or cannot be used with, any other product or for any other general purpose.

1.39. "Joint Product-Specific Patent Rights". Joint Product-Specific Patent Rights means all Patent Rights throughout the world covering Joint Product-Specific Know-How.

1.40. "Know-How". Know-How means any information and material that is confidential and proprietary, including, without limitation, ideas, concepts, discoveries, inventions, developments, improvements, know-how, trade secrets, designs, devices, equipment, process conditions, algorithms, notation systems, works of authorship, computer programs, technologies, formulas, techniques, methods, procedures, assay systems, applications, data, documentation, reports, sugars, polysaccharides, heparinases, enzymes, reagents, glycoproteins, proteins, peptides, glycoconjugates, primers, plasmids, vectors, expression systems, cells, cell lines, antibodies, organisms, chemical compounds, products and formulations, whether patentable or otherwise. Know-How shall also include non-confidential information and material to the extent such information and material first lost its confidentiality by virtue of its disclosure in an issued patent or published patent application, a filing with a Regulatory Authority or as part of a legal proceeding.

1.41. "Label". Label shall mean any package labeling designed for use with the Product, pursuant to the terms of this Agreement, in accordance with cGMP, including the package insert for such Product, that is approved by the FDA pursuant to the terms of this Agreement; and any variation of such term, such as "Labeled" or "Labeling", shall mean the act of doing the foregoing, and "Labeler" shall mean a Party or Third Party who performs the act of Labeling.

1.42. "Legal Activities". Legal Activities means (a) all Product-Specific Patent Activities, and (b) all activities with respect to Legal Clearance.

1.43. "Legal Clearance". Legal Clearance means collectively District Court Legal Clearance and Final Legal Clearance.

1.44. "Legal Clearance Costs". Legal Clearance Costs means all legal and related costs incurred to achieve Legal Clearance; provided, however, that Legal Clearance Costs specifically

exclude (a) Settlement Costs, and (b) the cost of any attorneys which Momenta independently involves in the activities to achieve Legal Clearance (which shall be the sole responsibility of Momenta), unless the JSC agrees that such costs should be included in Legal Clearance Costs.

1.45. "Legal Expenses". Legal Expenses means, with respect to the U.S. Territory: (a) Product-Specific Patent Costs; (b) Legal Clearance Costs; (c) all Liabilities related to Patent Litigation; (d) all Liabilities incurred by the Parties or the Indemnified Parties with respect to any claims described in Section 12.1(e); and (e) all Liabilities incurred by the Sandoz Parties with respect to any claims or demands related to the Product that are commenced by Aventis or any Third Party against any Sandoz Indemnified Party based on the activities of Momenta or the Sandoz Parties (including those undertaken by Affiliates or Third Parties on behalf of Momenta or the Sandoz Parties) [**] pursuant to this Agreement. Notwithstanding any provision to the contrary herein, Legal Expenses do not include: (i) damages (including [**]) due to Aventis as a result of a Pre Final Legal Clearance Launch; (ii) Product Liability Costs; and (iii) Settlement Costs.

1.46. "Locked Manufacturing Process". Locked Manufacturing Process means, with respect to the Product, an economically practical, highly controlled and highly reproducible manufacturing process that enables the manufacture of Characterized Product to FDA standards (including compatibility with cGMP) and in accordance with any ANDA requirements for the Product, including without limitation the Product's FDA specifications.

1.47. "Lovenox®-Equivalent Product". Lovenox®-Equivalent Product means (a) Lovenox® in injectable form sold as a brand, including Lovenox® sold by Aventis using another tradename, such as Clexane® (collectively, "Branded Lovenox"), or (b) any product sold in the U.S. Territory (other than Branded Lovenox) that is a generic AB-rated or AP-rated equivalent to Lovenox® in injectable form.

1.48. "Manufacturing Costs". Manufacturing Costs means, with respect to the Product, the aggregate of each Party's cost to commercially manufacture (including the buildup of commercial inventory) and/or Label the Product, calculated as follows: (a) if the Product is manufactured and/or Labeled by a Party or its Affiliate, then Manufacturing Costs shall be determined as set forth on Schedule 1.48; or (b) if the Product is manufactured and/or Labeled by a Third Party manufacturer, Manufacturing Costs shall equal the costs as invoiced by such Third Party manufacturer for the manufacture and/or Labeling of a specified quantity of the Product, plus any of the costs set forth on Schedule 1.48 that are incurred by the Parties or their Affiliates in completing the manufacture, Labeling and delivery to a warehouse(s) designated by the Sandoz Parties of such quantity of the Product.

If there are any Third Party Royalties payable hereunder, such amounts shall be considered a Manufacturing Cost for purposes of calculating any Profit Interest payable to Momenta hereunder.

1.49. "Marketing Approval". Marketing Approval means the approval of the FDA necessary and sufficient for the marketing and First Commercial Sale of the Product in the U.S. Territory.

1.50. "M118 Opportunity". M118 Opportunity means the research, development, manufacturing or commercialization of Momenta's low molecular weight heparin candidate known as M118.

1.51. "MIT". MIT means Massachusetts Institute of Technology.

1.52. "MIT Agreement". MIT Agreement means the Amended and Restated Exclusive Patent License Agreement by and between MIT and Momenta, dated as of November 1, 2002 and as amended by a First Amendment dated November 15, 2002 and letter agreements dated September 12, 2003 and October 22, 2003, as the same may be amended from time to time.

1.53. "Momenta Collaboration Know-How". Momenta Collaboration Know-How means (a) all Know-How constituting, based upon or derived from inventions or developments which are conceived and reduced to practice or developed solely by the employees, contractors (subject to Section 8.3), consultants or agents of Momenta or its Affiliates during, and in the conduct of, the Collaborative Program, excluding Improvements to Sandoz Know-How or Improvements to Sandoz Collaboration Know-How, and (b) (i) Improvements to Momenta Know-How or (ii) Improvements to Momenta Collaboration Know-How, which, with respect to each of (b)(i) and (b)(ii), are made solely by the employees, contractors, consultants or agents of Sandoz or its Affiliates, or jointly by the employees, contractors, consultants or agents of Sandoz or its Affiliates, on the one hand, and by the employees, contractors, consultants or agents of Momenta or its Affiliates, on the other hand, during, and in the conduct of, the Collaborative Program.

1.54. "Momenta Collaboration Patent Rights". Momenta Collaboration Patent Rights means all Patent Rights throughout the world covering Momenta Collaboration Know-How that are Controlled by Momenta.

1.55. "Momenta Indemnified Parties". Momenta Indemnified Parties means Momenta, Momenta's Affiliates, any of their successors or assigns, and any of their respective then-current or then-former directors, officers, employees, consultants, agents, suppliers, contract manufacturers, contract service providers, Third Parties engaged to perform activities under the Collaborative Program, and MIT (including MIT's trustees, officers, faculty, students, employees, and agents).

1.56. "Momenta IP". Momenta IP means Momenta Know-How, Momenta Collaboration Know-How, Momenta Patent Rights and Momenta Collaboration Patent Rights, including, without limitation, those license rights granted to Momenta under the MIT Agreement to the extent such would be included in Momenta Know-How, Momenta Collaboration Know-How, Momenta Patent Rights and Momenta Collaboration Patent Rights.

1.57. "Momenta Know-How". Momenta Know-How means all Know-How which (a) is Controlled by Momenta (i) as of the Effective Date or (ii) during the term of the Collaborative Program, but which is not developed or acquired by Momenta or any of its Affiliates in the conduct of the Collaborative Program, and (b) could reasonably be used in the conduct of the Collaborative Program.

1.58. "Momenta Patent Rights". Momenta Patent Rights means all Patent Rights throughout the world covering Momenta Know-How that are Controlled by Momenta, including, without limitation, the Patent Rights listed on Schedule 1.58.

1.59. "Momenta Product-Specific Know-How". Momenta Product-Specific Know-How means all Momenta Know-How or Momenta Collaboration Know-How which solely relates to the Product and does not relate, or cannot be used with, any other product or for any other general purpose.

1.60. "Momenta Product-Specific Patent Rights". Momenta Product-Specific Patent Rights means all Patent Rights throughout the world covering Momenta Product-Specific Know-How that are Controlled by Momenta.

1.61. "Net Sales". Net Sales means the gross amount invoiced by Sandoz or its Affiliates (or, with respect to Section 11.6.3, Momenta, its Affiliates and/or sublicensees) to Third Parties (whether an end-user, a distributor or otherwise) for sales of the Product, less: (a) the total value (to the extent actually allowed and taken directly with respect to such sales, as reflected in the amount invoiced) of trade, cash and quantity discounts and/or rebates, allowances, credits and charge backs, discounts in kind and/or other forms of consideration offered as inducements for the purchase of such Product, and/or required payments, including, without limitation, from (i) managed health care organizations, (ii) federal, state or local governmental agency programs (including Medicare and Medicaid or other similar programs in countries outside the U.S. Territory), their agencies and purchasers and reimbursers, and (iii) wholesalers and chain pharmacy buying groups and any other trade customers; and (b) any credits or allowances booked on account of shelfstock and other price adjustments, rejections or returns of Products previously sold; and (c) taxes, customs charges, duties and any other governmental charges, levied on, absorbed, or otherwise imposed on the production, importation, transportation, use or sale of the Product (excluding national, state or local taxes based on income); and (d) any Product recall costs, including Manufacturing Costs, costs of Product destruction and out-of-pocket administrative costs, that are not identifiable as being (x) the fault of the Sandoz Parties (in which case Sandoz shall be responsible for such costs) or (y) the fault of Momenta (in which case Momenta shall be responsible for such costs).

If there are any Third Party Royalties payable hereunder, such amounts shall be subtracted in order to arrive at Net Sales for purposes of all royalty payments to Momenta hereunder.

Such amounts shall be determined from the books and records of Sandoz or its Affiliates (or, with respect to Section 11.6.3, Momenta, its Affiliates and/or sublicensees), maintained in accordance with generally accepted accounting principles, consistently applied.

In the case of any sale of the Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of consideration received.

Each of the Sandoz Parties agrees not to use the Product as a loss leader. Each of the Sandoz Parties also agrees that if either of them price the Product in order to gain or maintain sales of other products, then for purposes of calculating the payments due hereunder, the Net Sales shall be adjusted to reverse any discount which was given to a customer that was in excess of

customary discounts for this Product (or, in the absence of relevant data for this Product, other similar products under similar market conditions), if such discount was given in order to gain or maintain sales of other products.

In the case of any sale of the Product between or among Sandoz or its Affiliates (or, with respect to Section 11.6.3, Momenta, its Affiliates and sublicensees) for resale, Net Sales shall be calculated as above only on the value charged or invoiced on the first arm's length sale thereafter to a Third Party.

1.62. "Non-Injectable or Improved Enoxaparin Opportunity". Non-Injectable or Improved Enoxaparin Opportunity means the research, development, manufacturing or commercialization of (a) enoxaparin to be administered [**] or (b) Improved Enoxaparin.

1.63. "Non-Owning Party". Non-Owning Party means, with respect to Sandoz IP, Momenta, and, with respect to Momenta IP, BCWI (or Sandoz, if so designated in writing by the Sandoz Parties).

1.64. "Non-U.S. Territory". Non-U.S. Territory means all countries outside the U.S. Territory.

1.65. "Owning Party". Owning Party means, with respect to Momenta IP, Momenta, and, with respect to Sandoz IP, BCWI (or Sandoz, if so designated in writing by the Sandoz Parties).

1.66. "Owning Party's IP". Owning Party's IP means, with respect to Momenta, the Momenta IP, and, with respect to a Sandoz Party, the Sandoz IP.

1.67. "Party". Party means Sandoz, BCWI or Momenta; "Parties" means Sandoz, BCWI and Momenta.

1.68. "Patent Litigation". Patent Litigation means (a) a claim or demand by Aventis that alleges patent infringement against any Momenta Indemnified Party or any Sandoz Indemnified Party based on (i) the activities of the Sandoz Parties or Momenta (including those undertaken by Affiliates or Third Parties on behalf of them) pursuant to this Agreement related to the Product (including the manufacture of the Product), or (ii) the activities of the Sandoz Parties or Momenta (including those undertaken by Affiliates or Third Parties on behalf of them) [**] related to the Product (including the manufacture of the Product), or (b) a declaratory judgment or other legal or equitable proceeding approved by the JSC (or if the JSC cannot reach agreement, through the provisions of Article 13) and commenced or joined by Momenta, Sandoz or one of their Affiliates that seeks a judgment against Aventis that Sandoz, Momenta, their Affiliates and/or Momenta's licensees have not infringed, or will not infringe, any patent related to the Product (including the manufacture of the Product), in each case, irrespective of the nature of the relief sought (which may include, without limitation, actual, consequential or enhanced damages) and irrespective of the jurisdiction in which such claim, demand or action is brought.

1.69. "Patent Right". Patent Right means a United States and/or foreign patent or patent application and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof.

1.70. "Person". Person means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.

1.71. "Post-Launch Quarter". Post-Launch Quarter means the Quarter in which U.S. Launch Occurs (the "First Post-Launch Quarter") or each subsequent Quarter (referred to as the "Second Post-Launch Quarter", "Third Post-Launch Quarter", etc.).

1.72. "Post-Launch Year". Post-Launch Year means each four Post-Launch Quarter period, with the First Post-Launch Year encompassing the period of the First Post-Launch Quarter through the Fourth Post-Launch Quarter, the Second Post-Launch Year encompassing the period of the Fifth Post-Launch Quarter through the Eighth Post-Launch Quarter, etc.

1.73. "Pre Final Legal Clearance Launch". Pre Final Legal Clearance Launch means the occurrence of the U.S. Launch prior to Final Legal Clearance. For the avoidance of doubt, any such launch shall be in the sole discretion of Sandoz.

1.74. "Product". Product means injectable enoxaparin and any improved injectable form of enoxaparin for which Lovenox®, as defined in the relevant New Drug Application approved as of the Effective Date or any past or future Supplemental New Drug Applications, is the reference listed drug and for which an ANDA could be approved by the FDA, but specifically excluding any Improved Enoxaparin. "Product" includes, without limitation, a Lovenox®-Equivalent Product developed by the Parties pursuant to this Agreement.

1.75. "Product Liability Costs". Product Liability Costs means all Liabilities incurred by any Momenta Indemnified Party or Sandoz Indemnified Party arising from actual or alleged product liability with respect to the Product, including, without limitation, any such Liabilities incurred or paid by the Parties or the Indemnified Parties with respect to any claims described in Sections 12.1(d) or 12.1(e) (as applicable).

1.76. "Product-Specific Patent Activities". Product-Specific Patent Activities means all activities of the Parties with respect to the preparation, filing, prosecution, maintenance, enforcement and invalidity defense of Product-Specific Patent Rights to the extent such Product-Specific Patent Rights are relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1.

1.77. "Product-Specific Patent Costs". Product-Specific Patent Costs means all costs paid by a Party to Third Parties with respect to the Product-Specific Patent Activities.

1.78. "Product-Specific Patent Rights". Product-Specific Patent Rights means Sandoz Product-Specific Patent Rights, Momenta Product-Specific Patent Rights and Joint Product-Specific Patent Rights.

1.79. "Profits". Profits means Net Sales less (a) Selling Expenses and (b) Manufacturing Costs for the Product sold (regardless of whether the Product is rejected, returned or recalled).

1.80. "Project Leader". Project Leader means an executive appointed by Momenta, on the one hand, or the Sandoz Parties, on the other hand, to serve as such Party's principal coordinator and liaison for the Collaborative Program. The Project Leader appointed by the Sandoz Parties is referred to as the "Sandoz Project Leader" and the Project Leader appointed by Momenta is referred to as the "Momenta Project Leader."

1.81. "Quarter". Quarter means each three month period ending March 31, June 30, September 30 and December 31 in each calendar year.

1.82. "Regulatory Authority". Regulatory Authority means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, manufacture, use, storage, import, promotion, marketing and sale of a therapeutic product in a country, including the FDA.

1.83. "Sandoz Collaboration Know-How". Sandoz Collaboration Know-How means (a) all Know-How constituting, based upon or derived from inventions or developments which are conceived and reduced to practice or developed solely by the employees, contractors (subject to Section 8.3), consultants or agents of Sandoz or its Affiliates during, and in the conduct of, the Collaborative Program, excluding Improvements to Momenta Know-How or Improvements to Momenta Collaboration Know-How, and (b) (i) Improvements to Sandoz Know-How or (ii) Improvements to Sandoz Collaboration Know-How, which, with respect to each of (b)(i) and (b)(ii), are made solely by the employees, contractors, consultants or agents of Momenta or its Affiliates, or jointly by the employees, contractors, consultants or agents of Sandoz or its Affiliates, on the one hand, and by the employees, contractors, consultants or agents of Momenta or its Affiliates, on the other hand, during, and in the conduct of, the Collaborative Program.

1.84. "Sandoz Collaboration Patent Rights". Sandoz Collaboration Patent Rights means all Patent Rights throughout the world covering Sandoz Collaboration Know-How that are Controlled by a Sandoz Party.

1.85. "Sandoz Indemnified Parties". Sandoz Indemnified Parties means Sandoz, BCWI, their Affiliates, any of their successors or assigns, and any of their respective then-current or then-former directors, officers, employees, consultants, suppliers, contract manufacturers, contract service providers, and Third Parties engaged to perform activities under the Collaborative Program.

1.86. "Sandoz IP". Sandoz IP means Sandoz Know-How, Sandoz Collaboration Know-How, Sandoz Patent Rights and Sandoz Collaboration Patent Rights. Sandoz IP expressly excludes the intellectual property rights of any Affiliate of the Sandoz Parties, unless such intellectual property rights are Controlled by a Sandoz Party, it being understood that the Sandoz Parties shall have the obligation to obtain Control set forth in Section 8.3.

1.87. "Sandoz Know-How". Sandoz Know-How means all Know-How which (a) is Controlled by a Sandoz Party (i) as of the Effective Date or (ii) during the term of the Collaborative Program, but which is not developed by Sandoz or its Affiliates or acquired by Sandoz or its Affiliates in the conduct of the Collaborative Program, and (b) is contributed and approved for use by a Sandoz Party in the conduct of the Collaborative Program, it being understood that any such contribution shall be in the sole discretion of such Sandoz Party and that, unless the Parties otherwise agree in writing, such Sandoz Party shall not charge Momenta for any such contribution.

1.88. "Sandoz Patent Rights". Sandoz Patent Rights means all Patent Rights throughout the world covering Sandoz Know-How that are Controlled by a Sandoz Party.

1.89. "Sandoz Product-Specific Know-How". Sandoz Product-Specific Know-How means all Sandoz Know-How or Sandoz Collaboration Know-How which solely relates to the Product and does not relate, or cannot be used with, any other product or for any other general purpose.

1.90. "Sandoz Product-Specific Patent Rights". Sandoz Product-Specific Patent Rights means all Patent Rights throughout the world covering Sandoz Product-Specific Know-How that are Controlled by a Sandoz Party.

1.91. "Selling Expenses". Selling Expenses means Sandoz's or its Affiliates' expenditures to market, distribute and sell the Product, which shall be deemed for purposes of this Agreement to be equal to [**] percent ([**]%) of Net Sales of such Product for each applicable period.

1.92. "Settlement". Settlement means an agreement or settlement, made at any time, between a Sandoz Party or its Affiliate(s), on the one hand, and Aventis, on the other hand, that finally resolves any existing Patent Litigation and precludes any future Patent Litigation by Aventis against the Sandoz Parties, their Affiliates and the Momenta Indemnified Parties related to the Product, such that the Product may be marketed by or continue to be marketed by or on behalf of Sandoz or its Affiliates subject to ANDA Final Approval of an ANDA filed by Sandoz or any of its Affiliates for the Product.

1.93. "Settlement Costs". Settlement Costs means all amounts paid to Aventis (whether [**] or similar arrangement, including without limitation [**] in accordance with Section 6.2.2) in order to achieve a Settlement.

1.94. "Stability Studies". Stability Studies means, with respect to the Product, the performance of stability testing at one-tenth commercial scale in accordance with the stability protocol set forth in the ANDA for the Product.

1.95. "Supply Chain". Supply Chain, with respect to Product, means stable, reliable, and commercially practical sources to obtain all starting materials, biological products, biological molecules, chemicals, precursors, intermediates, and reagents of sufficient quantity, quality, and purity necessary to manufacture the required commercial quantities of the Product according to the Locked Manufacturing Process. "Supply Chain" includes commercial sources

of all packaging components and packaging materials, including primary and printed packaging materials according to the standards set forth in the ANDA for the Product.

1.96. "Third Party". Third Party means any Person other than a Party or any of its Affiliates.

1.97. "Third-Party Competitor". Third-Party Competitor means each Third Party (including, [**], collectively with all of such Third Party's Affiliates, licensees and/or distributors, which Third Party owns, itself or through its Affiliates, [**] in the U.S. Territory for [**] Products and which Third Party is marketing, itself or through its Affiliates, licensees and/or distributors, [**] in the U.S. Territory; provided, however, that Third-Party Competitor shall exclude Sandoz's and BCWI's Affiliates and distributors. If [**], it shall be termed the "[**]".

1.98. "Third Party Royalties". Third Party Royalties means any royalties, license fees or other monetary payments made by the Sandoz Parties (either directly or via reimbursement to Momenta) to any Third Party in consideration of a license(s) under such Third Party patent(s), know-how or other intellectual property rights, when such license is reasonably determined by the JPT to be necessary to commercially manufacture and/or sell the Product without infringing such Third Party intellectual property rights; provided, however, that Third Party Royalties shall not include any payments to Third Party contractors hired by Momenta or any Sandoz Parties, with prior approval of the JPT, in order to provide services in connection with Development activities under this Agreement, under which royalty-free licenses are granted to intellectual property created during the course of providing such services.

1.99. "U.S. Launch". U.S. Launch means the time when Sandoz, its Affiliates or distributors achieve the First Commercial Sale of the Product in the U.S. Territory.

1.100. "U.S. Territory". U.S. Territory shall mean the fifty states of the United States of America, the District of Columbia and all territories and possessions of the United States of America and any other location where the FDA has jurisdiction over medicinal products intended for human use.

1.101. Other Defined Terms. Each of the following definitions is set forth in the section of this Agreement indicated below:

Definition	Section
Actual Momenta Economic Interest	Schedule 4.3
Additional Excessive Cost Termination	11.5.2
Additional Excessive Cost Termination Option Period	11.5.2
Additional Excessive Cost Trigger	11.5.2
Additional FTE's	4.2
Agreement	Preamble
Aventis Persons	1.6
Aventis [**]	1.97
Aventis [**]	4.8.1
BCWI	Preamble

BCWI Executive Officer	1.25
Branded Lovenox	1.47
Carryforward	Schedule 4.3
Commercial Milestone Payments	4.10.2
Commercial Viability Termination	11.3
Commercial Viability Trigger	11.3
Controlled Contractors	3.1
Cost Cap	4.1
Disclosing Party	10.2
District Court	1.23
District Court Decision	1.23
Economic Interest Variance	Schedule 4.3
Entire Capacity	Schedule 1.48
Effective Date	Preamble
FD&C Act	1.3
Final Misappropriation Determination	12.2
Force Majeure Event	14.15
Fragmin Notice	3.1
Fragmin Response	3.1
Fragmin Response Period	3.1
FTE Records	4.2
Full Capacity	Schedule 1.48
Full Milestone Payment(s)	4.10.2
Indemnified Party	12.3
Indemnifying Party	12.3
Initial Excessive Cost Termination	11.5.1
Initial Excessive Cost Termination Option Period	11.5.1
Initial Excessive Cost Trigger	11.5.1
Initial Non-U.S. Territory Negotiation Period	3.4.2
Invalidity Claim	8.6
Joint Project Team / JPT	5.2
Labeler	1.41
Joint Steering Committee / JSC	5.3
Legal Strategy Diminishment	11.4
Liabilities	12.1
Milestone Payment Quarter	4.10.2
M118 Notice	3.2
M118 Response	3.2
M118 Response Period	3.2
MIT Associates	14.16
Momenta	Preamble
Momenta Assigned Improvements	8.1.1
Momenta Economic Interest	Schedule 4.3
Momenta Executive Officer	1.25

Momenta Project Leader	1.80
Momenta Share of Excess Costs	Schedule 4.3
New Excess Costs	Schedule 4.3
[**] Period	4.7.1
[**] Royalty	4.7.1
Non-Injectable or Improved Enoxaparin Response	3.3.1
Non-Injectable or Improved Enoxaparin Notice	3.3.1
Non-Injectable or Improved Enoxaparin Response Period	3.3.1
Non-U.S. Option	3.4.1
Non-U.S. Option Period	3.4.1
Non-U.S. Territory Agreement	3.4.2
[**] Period	4.5
Orange Book Litigation	1.28
Pleadings	12.3.3
Post-[**] Period	4.6.1
Post-[**] Royalty	4.6.1
Pre-Existing Costs	1.21
Prior Confidentiality Agreement	10.1
Product Records	4.11.4
Profit Interest	4.5
Program Output	3.4.6
Receiving Party	10.2
Regulatory Milestone Payment	4.10.1
Representing Party	9.1
Sandoz	Preamble
Sandoz Assigned Improvements	8.1.1
Sandoz Executive Officer	1.25
Sandoz Party	Preamble
Sandoz Parties	Preamble
Sandoz Milestone Termination	11.4
Sandoz Milestone Trigger	11.4
Sandoz Parties Royalty	11.6.3
Sandoz Project Leader	1.80
Supply Continuation Plan	11.2.2
Supply Interruption	11.2.2
Supply Interruption Notice	11.2.2
Term	11.1
Third Party Term Sheet	3.4.5
Third Party Term Sheet Notice	3.4.5
True-Up Amount	Schedule 4.3

2. GRANT OF RIGHTS

2.1. Momenta License Grants. Subject to the terms and conditions of this Agreement, Momenta hereby grants to BCWI during the Term, (a) an exclusive license, without the right to grant sublicenses, under Momenta IP and under Momenta's rights in the Joint Collaboration IP, to Develop, make, have made, use, sell, offer to sell, lease, import and export the Product in the U.S. Territory in the Field, and (b) a non-exclusive license, with no right to grant sublicenses, under the Momenta IP to make, have made, and use the Product in the Non-U.S. Territory, but only for the purposes of sale of the Product in or into the U.S. Territory; provided, however, that Momenta retains the right to practice, and to grant sublicenses, under Momenta IP and under Momenta's rights in the Joint Collaboration IP in the U.S. Territory in the Field to (i) perform its obligations to the Sandoz Parties under this Agreement, including, without limitation, to conduct the Momenta activities under this Agreement and in the Annual Collaboration Plans and (ii) make and have made the Product in the U.S. Territory solely for the purposes of sales of the Product in the Field (A) in those countries in the Non-U.S. Territory for which Sandoz does not, during the Non-U.S. Option Period, exercise the Non-U.S. Option, or (B) if Sandoz exercises the Non-U.S. Option within the Non-U.S. Option Period, in those countries in the Non-U.S. Territory for which Sandoz and Momenta do not execute a Non-U.S. Territory Agreement either during the Initial Non-U.S. Territory Negotiation Period or pursuant to Section 3.4.5. Notwithstanding the foregoing prohibition on sublicensing, (a) BCWI may sublicense its rights under this Section 2.1 to Sandoz to the extent it deems necessary for Sandoz to perform its obligations under this Agreement, and (b) subject to the provisions of Section 8.3.3, BCWI may sublicense its rights under this Section 2.1 to an Affiliate of BCWI other than Sandoz to the extent as may be permitted under the Annual Collaboration Plans or as otherwise approved in writing by Momenta.

2.2. Sandoz Parties License Grants. Subject to the terms and conditions of this Agreement, the Sandoz Parties hereby grant to Momenta, during the term of this Agreement, a worldwide, non-exclusive, royalty-free license, without the right to grant sublicenses (except to the extent as may be permitted under the relevant Annual Collaboration Plan or as otherwise approved in writing by the relevant Sandoz Party) under Sandoz IP and under the Sandoz Parties' rights in the Joint Collaboration IP, solely to the extent necessary or appropriate to perform Momenta's obligations to the Sandoz Parties under this Agreement, including, without limitation, to conduct the Momenta activities under this Agreement and in the Annual Collaboration Plans.

2.3. Exclusivity. Subject to Momenta's retained right in Section 2.1, except as otherwise agreed in writing by the Parties, Momenta agrees that it shall not, and shall ensure that its Affiliates do not, during the Term, grant any license in Momenta IP or Joint Collaboration IP to any Third Party to Develop, make, have made, use, sell, offer to sell, lease, import, export or otherwise Commercialize the Product in the Field in the U.S. Territory. Except as otherwise agreed in writing by the Parties, each Sandoz Party agrees that it shall not, and shall use reasonable efforts to cause its Affiliates not to, during the Term, grant any license to any Third Party to Develop, make, have made, use, sell, offer to sell, lease, import, export or otherwise Commercialize the Product in the Field in the U.S. Territory, except to the extent necessary or appropriate to perform the Sandoz Parties' obligations to Momenta under this Agreement;

provided, however, that if an Affiliate of any Sandoz Party grants any such license to any Third Party, it shall be considered a breach of this Agreement by the Sandoz Parties. Momenta shall, and shall ensure that its Affiliates, exclusively develop and Commercialize the Product with the Sandoz Parties during the Term in the U.S. Territory. Each Sandoz Party shall, and shall use reasonable efforts to ensure that its Affiliates, exclusively develop and Commercialize the Product with Momenta during the Term in the U.S. Territory; provided, however, that if an Affiliate of any Sandoz Party develops or commercializes the Product without Momenta during the Term in the U.S. Territory, it shall be considered a breach of this Agreement by the Sandoz Parties.

2.4. Retained Rights. Any rights of Momenta not expressly granted to Sandoz or BCWI under the provisions of this Agreement shall be retained by Momenta and any rights of Sandoz or BCWI not expressly granted to Momenta under the provisions of this Agreement shall be retained by Sandoz or BCWI, respectively.

2.5. Third Party Licensor Rights. The rights granted in Sections 2.1 and 2.2 are granted to the extent permitted or qualified by the nature of the licenses granted by the relevant Third Party licensors, if any, of Momenta IP or Sandoz IP, as the case may be. The Party receiving such license shall comply with all restrictions and obligations imposed by such Third Party licensors; provided, however, that, if Momenta or a Sandoz Party, as the case may be, enters into a license with a Third Party licensor for any intellectual property that may be considered Momenta IP or Sandoz IP, respectively, Momenta or such Sandoz Party shall notify the Sandoz Parties or Momenta, respectively, of the restrictions and obligations imposed by such Third Party licensor, and, if the Sandoz Parties or Momenta, respectively, do not wish to comply with such restrictions and obligations, such licensed intellectual property shall not be considered Momenta IP or Sandoz IP, respectively, hereunder. Sandoz acknowledges receipt of a copy of the MIT Agreement from Momenta. Momenta represents that the copy of the MIT Agreement delivered to Sandoz in accordance with the foregoing represents the MIT Agreement as in effect as of the Effective Date.

3. ADDITIONAL RIGHTS

3.1. Fragmin Opportunity; Right of First Negotiation. During the Term, prior to entering into any detailed negotiations regarding key terms and/or entering into any contract, agreement, term sheet, understanding or arrangement (verbal or written) with a Commercial Third Party (other than Third Party contractors such as contract research organizations, contract manufacturers, contract employees, consultants and the like which merely conduct activities on behalf of Momenta and subject to Momenta's supervision and control ("Controlled Contractors")) with respect to a Fragmin Opportunity in the U.S. Territory or the Non-U.S. Territory, Momenta shall provide written notice to the Sandoz Parties of its bona fide present intent to engage in such activities at such time (the "Fragmin Notice"), which Fragmin Notice shall include information in reasonable detail sufficient to enable the Sandoz Parties to make an informed decision with respect to such Fragmin Opportunity; provided, however, that this Section 3.1 shall not prevent Momenta from participating in general discussions or negotiations with Third Parties with respect to a Fragmin Opportunity in the U.S. Territory or the Non-U.S. Territory. If either (but not both) of the Sandoz Parties notifies Momenta in writing within thirty

(30) days of receipt of the Fragmin Notice (the "Fragmin Response Period", such notice, the "Fragmin Response") that it has a bona fide interest in discussing a collaboration with Momenta with respect to such Fragmin Opportunity, Momenta and such Sandoz Party shall enter into good faith negotiations on an exclusive basis, on such terms as may be mutually agreeable. If (a) neither Sandoz Party indicates during the Fragmin Response Period that it is interested in discussing such Fragmin Opportunity, (b) the Sandoz Parties indicate in writing during the Fragmin Response Period that they have no interest in such Fragmin Opportunity, or (c) one of the Sandoz Parties indicates such an interest during the Fragmin Response Period but Momenta and such Sandoz Party are unable, after good faith negotiations, to reach mutual agreement and execute a definitive agreement with respect to a collaboration with respect to such Fragmin Opportunity within [**] from the date of the Fragmin Response (or such extended period as may be approved in writing by Momenta and such Sandoz Party), Momenta shall be free for a period of [**] thereafter to undertake detailed negotiations regarding key terms and enter into a transaction (including execution of a definitive agreement) relating to such Fragmin Opportunity with a Commercial Third Party(ies), which, with respect only to clause (c) above, shall be on terms not less favorable, taken as a whole, to Momenta than those last offered to the applicable Sandoz Party. Momenta and the Sandoz Parties recognize that, in evaluating the favorability to Momenta of the terms of such Third Party transaction relating to such Fragmin Opportunity, numerous factors may be taken into account and given appropriate weight, including, without limitation, the amount of up-front payments, the amount and timing of subsequent license or research payments, the royalty rate(s) or profit sharing terms, the definition of territory, marketing and promotion rights, the purchase and pricing of equity, if applicable, and the identity, experience and market position of such Third Party(ies) in the relevant markets. If, after the expiration of such [**] period, Momenta has not entered into a transaction with any Third Party with respect to such Fragmin Opportunity, then Momenta and the Sandoz Parties shall again follow the procedures described in this Section 3.1 with respect to such Fragmin Opportunity. Momenta shall not be obligated to reveal to the Sandoz Parties the identity of any Third Party involved in any such transaction.

3.2. M118 Opportunity; Right of First Negotiation. During the Term, prior to entering into any detailed negotiations regarding key terms and/or entering into any contract, agreement, term sheet, understanding or arrangement (verbal or written) with a Commercial Third Party (other than Controlled Contractors) with respect to an M118 Opportunity in the U.S. Territory or the Non-U.S. Territory, Momenta shall provide written notice to the Sandoz Parties of its bona fide present intent to engage in such activities at such time (the "M118 Notice"), which M118 Notice shall include information in reasonable detail sufficient to enable the Sandoz Parties to make an informed decision with respect to such M118 Opportunity; provided, however, that this Section 3.2 shall not prevent Momenta from participating in general discussions or negotiations with Third Parties with respect to an M118 Opportunity in the U.S. Territory or the Non-U.S. Territory. If either (but not both) of the Sandoz Parties notifies Momenta in writing within thirty (30) days of receipt of the M118 Notice (the "M118 Response Period", such notice, the "M118 Response") that it has a bona fide interest in discussing a collaboration with Momenta with respect to such M118 Opportunity, Momenta and such Sandoz Party shall enter into good faith negotiations on an exclusive basis, on such terms as may be mutually agreeable. If (a) neither Sandoz Party indicates during the M118 Response Period that it is interested in discussing such M118 Opportunity, (b) the Sandoz Parties indicate in writing during the M118 Response Period

that they have no interest in such M118 Opportunity, or (c) one of the Sandoz Parties indicates such an interest during the M118 Response Period but Momenta and such Sandoz Party are unable, after good faith negotiations, to reach mutual agreement and execute a definitive agreement with respect to a collaboration with respect to such M118 Opportunity within [**] from the date of the M118 Response (or such extended period as may be approved in writing by Momenta and such Sandoz Party), Momenta shall be free for a period of [**] thereafter to undertake detailed negotiations regarding key terms and enter into a transaction (including execution of a definitive agreement) relating to such M118 Opportunity with a Commercial Third Party(ies), which, with respect only to clause (c) above, shall be on terms not less favorable, taken as a whole, to Momenta than those last offered to the applicable Sandoz Party. Momenta and the Sandoz Parties recognize that, in evaluating the favorability to Momenta of the terms of such Third Party transaction relating to such M118 Opportunity, numerous factors may be taken into account and given appropriate weight, including, without limitation, the amount of up-front payments, the amount and timing of subsequent license or research payments, the royalty rate(s) or profit sharing terms, the definition of territory, marketing and promotion rights, the purchase and pricing of equity, if applicable, and the identity, experience and market position of such Third Party(ies) in the relevant markets. If, after the expiration of such [**] period, Momenta has not entered into a transaction with any Third Party with respect to such M118 Opportunity, then Momenta and the Sandoz Parties shall again follow the procedures described in this Section 3.2 with respect to such M118 Opportunity. Momenta shall not be obligated to reveal to the Sandoz Parties the identity of any Third Party involved in any such transaction.

3.3. Non-Injectable or Improved Enoxaparin Opportunities.

3.3.1 U.S. Territory. If, during the Term, Momenta intends to begin detailed negotiations regarding key terms and/or enter into any contract, agreement, term sheet, understanding or arrangement (verbal or written) with a Commercial Third Party (other than Controlled Contractors) with respect to a Non-Injectable or Improved Enoxaparin Opportunity in the U.S. Territory, Momenta shall provide written notice of such bona fide present intent to the Sandoz Parties (the "Non-Injectable or Improved Enoxaparin Notice"), which Non-Injectable or Improved Enoxaparin Notice shall include information in reasonable detail sufficient to enable the Sandoz Parties to make an informed decision with respect to such Non-Injectable or Improved Enoxaparin Opportunity; provided, however, that this Section 3.3 shall not prevent Momenta from participating in general discussions or negotiations with Third Parties with respect to a Non-Injectable or Improved Enoxaparin Opportunity in the U.S. Territory. If either (but not both) of the Sandoz Parties notifies Momenta in writing within [**] of receipt of the Non-Injectable or Improved Enoxaparin Notice (the "Non-Injectable or Improved Enoxaparin Response Period", such notice, the "Non-Injectable or Improved Enoxaparin Response") that it has a bona fide interest in discussing a collaboration with Momenta with respect to such Non-Injectable or Improved Enoxaparin Opportunity, Momenta and such Sandoz Party shall enter into good faith negotiations on an exclusive basis, on such terms as may be mutually agreeable. If (a) neither Sandoz Party indicates during the Non-Injectable or Improved Enoxaparin Response Period that it is interested in discussing such

Non-Injectable or Improved Enoxaparin Opportunity, (b) the Sandoz Parties indicate in writing during the Non-Injectable or Improved Enoxaparin Response Period that they have no interest in such Non-Injectable or Improved Enoxaparin Opportunity, or (c) one of the Sandoz Parties indicates such an interest during the Non-Injectable or Improved Enoxaparin Response Period but Momenta and such Sandoz Party are unable to, after good faith negotiations, reach mutual agreement and execute a definitive agreement with respect to a collaboration with respect to such Non-Injectable or Improved Enoxaparin Opportunity within [**] from the date of the Non-Injectable or Improved Enoxaparin Response (or such extended period as may be approved in writing by Momenta and such Sandoz Party), Momenta shall be free for a period of [**] thereafter, to undertake detailed negotiations regarding key terms and/or enter into a transaction (including execution of a definitive agreement) relating to such Non-Injectable or Improved Enoxaparin Opportunity with a Commercial Third Party(ies), which, with respect only to clause (c) above, shall be on terms not less favorable, taken as a whole, to Momenta than those last offered to the applicable Sandoz Party. Momenta and the Sandoz Parties recognize that, in evaluating the favorability to Momenta of the terms of such Third Party transaction relating to such Non-Injectable or Improved Enoxaparin Opportunity, numerous factors may be taken into account and given appropriate weight, including, without limitation, the amount of up-front payments, the amount and timing of subsequent license or research payments, the royalty rate(s) or profit sharing terms, the definition of territory, marketing and promotion rights, the purchase and pricing of equity, if applicable, and the identity, experience and market position of such Third Party(ies) in the relevant markets. If, after the expiration of such [**] period, Momenta has not entered into a transaction with any Third Party with respect to such Non-Injectable or Improved Enoxaparin Opportunity, then Momenta and the Sandoz Parties shall again follow the procedures described in this Section 3.3.1 with respect to such Non-Injectable or Improved Enoxaparin Opportunity. Momenta shall not be obligated to reveal to the Sandoz Parties the identity of any Third Party involved in any such transaction.

3.3.2 Non-U.S. Territory.

a. During the Non-U.S. Option Period, Momenta shall provide a Non-Injectable or Improved Enoxaparin Notice under Section 3.3.1 to the Sandoz Parties if Momenta has a bona fide present intent to begin detailed negotiations regarding key terms or enter into any contract, agreement, term sheet, understanding or arrangement (verbal or written) with a Commercial Third Party at such time with respect to a Non-Injectable or Improved Enoxaparin Opportunity in the Non-U.S. Territory, and the provisions of Section 3.3.1 shall apply *mutatis mutandis* with respect to the Non-U.S. Territory.

b. During the Initial Non-U.S. Territory Negotiation Period, if any, and during the term of the Non-U.S. Territory Agreement, Momenta shall provide a Non-Injectable or Improved Enoxaparin Notice under

Section 3.3.1 to the Sandoz Parties if Momenta has a bona fide present intent to begin detailed negotiations regarding key terms or enter into any contract, agreement, term sheet, understanding or arrangement (verbal or written) with a Commercial Third Party at such time with respect to a Non-Injectable or Improved Enoxaparin Opportunity in the portion of the Non-U.S. Territory for which a Sandoz Party has exercised the Non-U.S. Option or executed the Non-U.S. Territory Agreement, as applicable, and the provisions of Section 3.3.1 shall apply with respect to such countries.

c. Notwithstanding the provisions of Sections 3.3.2(a) and 3.3.2(b), (i) if neither Sandoz Party indicates during the Non-U.S. Option Period that it is interested in exercising the Non-U.S. Option or the Sandoz Parties indicate in writing during the Non-U.S. Option Period that they have no interest in exercising the Non-U.S. Option, Momenta shall have no further obligations to the Sandoz Parties or their Affiliates with respect to the Non-Injectable or Improved Enoxaparin Opportunity in the Non-U.S. Territory; (ii) Momenta shall not be obligated to enter into definitive agreements with a Sandoz Party with respect to a Non-Injectable or Improved Enoxaparin Opportunity in the Non-U.S. Territory unless and until Momenta and a Sandoz Party have entered into the Non-U.S. Territory Agreement; provided, however, that the negotiation period for any such Non-Injectable or Improved Enoxaparin Opportunity in the Non-U.S. Territory shall be tolled without penalty during the Non-U.S. Option Period and the Initial Non-U.S. Territory Negotiation Period; (iii) if a Sandoz Party exercises the Non-U.S. Option but Momenta and such Sandoz Party do not enter into the Non-U.S. Territory Agreement either prior to the expiration of the Initial Non-U.S. Territory Negotiation Period or pursuant to Section 3.4.5, Momenta shall have no further obligations to the Sandoz Parties or their Affiliates with respect to the Non-Injectable or Improved Enoxaparin Opportunity in the Non-U.S. Territory; (iv) if a Sandoz Party exercises the Non-U.S. Option with respect to only a portion of the Non-U.S. Territory, Momenta shall have no further obligations to the Sandoz Parties or their Affiliates with respect to a Non-Injectable or Improved Enoxaparin Opportunity with respect to those countries in the Non-U.S. Territory for which a Sandoz Party did not exercise the Non-U.S. Option; and (v) this Section 3.3 shall not prevent Momenta from participating in general discussions or negotiations with Third Parties with respect to a Non-Injectable or Improved Enoxaparin Opportunity in the Non-U.S. Territory.

3.4. Non-U.S. Territory Option.

3.4.1 Option. Momenta hereby grants to either (but not both) of the Sandoz Parties the exclusive option to commence negotiations to obtain an exclusive license to Develop and Commercialize the Product in all or part of the Non-U.S. Territory on terms to be determined in accordance with the provisions of this Section 3.4 (the "Non-U.S. Option"). A Sandoz Party shall notify Momenta in

writing as to its exercise of the Non-U.S. Option within four (4) months after the Effective Date (the "Non-U.S. Option Period"). During the Non-U.S. Option Period, no Party shall, and each Party shall ensure that its Affiliates do not, develop or commercialize the Product with a Third Party in the Non-U.S. Territory. During the Initial Non-U.S. Negotiation Period, if any, no Party shall, and each Party shall ensure that its Affiliates do not, develop or commercialize the Product with a Third Party in the portion of the Non-U.S. Territory for which a Sandoz Party has exercised the Non-U.S. Option.

3.4.2 Initial Non-U.S. Territory Negotiation Period. Upon exercise by a Sandoz Party of the Non-U.S. Option, Momenta and such Sandoz Party shall negotiate in good faith a definitive agreement containing terms and conditions for the exclusive license in the portion of the Non-U.S. Territory for which such Sandoz Party has exercised the Non-U.S. Option in Section 3.4.1 (the "Non-U.S. Territory Agreement"). Unless extended by mutual agreement of Momenta and such Sandoz Party, the negotiations shall cease after the first anniversary of the Effective Date (the "Initial Non-U.S. Territory Negotiation Period") if the Parties have not entered into the Non-U.S. Territory Agreement by such time.

3.4.3 Agreed Terms. Momenta and the Sandoz Parties agree that the Non-U.S. Territory Agreement will (a) be generally consistent with the terms of this Agreement (provided, however, that the Non-U.S. Territory Agreement will, unless otherwise agreed by Momenta and the applicable Sandoz Party, permit sublicensing of marketing rights, and, if sublicensing of marketing rights by a Sandoz Party is permitted, the Non-U.S. Territory Agreement shall include such Sandoz Party's payment to Momenta of a mutually agreed percentage of any payment received by the Sandoz Party from a sublicense of the Product; and provided further that the Non-U.S. Territory Agreement shall include provisions specific to the relevant countries and/or to inter-jurisdictional agreements, which may include, without limitation, provisions with respect to tax withholding and addressing legal restrictions on inter-jurisdictional payments, as applicable), (b) take into consideration the economics of the international markets for enoxaparin, and (c) not include upfront payments or Development-related milestone payments.

3.4.4 Non-Exercise of Option. If the Sandoz Parties elect not to exercise the Non-U.S. Option pursuant to Section 3.4.1 within the Non-U.S. Option Period, or elect to exercise the Non-U.S. Option with respect to only a portion of the Non-U.S. Territory, on a country-by-country basis, Momenta shall be free to begin discussions or negotiations and/or enter into any contract, agreement, understanding or arrangement with Third Parties relating to the Development and/or Commercialization of the Product in the Non-U.S. Territory or, if applicable, the portion of the Non-U.S. Territory as to which the Sandoz Parties did not exercise the Non-U.S. Option.

3.4.5 Failure to Reach Agreement; Right of First Refusal. If a Sandoz Party exercises the Non-U.S. Option but Momenta and such Sandoz Party do not enter into the Non-U.S. Territory Agreement prior to the expiration of the Initial Non-U.S. Territory Negotiation Period, Momenta shall be free to begin discussions or negotiations with Third Parties relating to the Development and/or Commercialization of the Product in the portion of the Non-U.S. Territory for which a Sandoz Party has exercised the Non-U.S. Option; provided that Momenta will not enter into any contract, agreement, term sheet, understanding or arrangement with a Commercial Third Party relating to the Development and/or Commercialization of the Product in the portion of the Non-U.S. Territory for which such Sandoz Party has exercised the Non-U.S. Option without first complying with the following procedures: At such time as Momenta has reached agreement on key terms with a Third Party relating to the Development and/or Commercialization of the Product in the portion of the Non-U.S. Territory for which a Sandoz Party has exercised the Non-U.S. Option (a "Third Party Term Sheet"), Momenta shall provide a copy of such Third Party Term Sheet (which may be redacted to delete the name of the Third Party) to the applicable Sandoz Party (a "Third Party Term Sheet Notice"). Within [**] after receipt of a Third Party Term Sheet Notice, such Sandoz Party shall indicate in writing to Momenta whether it wishes to negotiate and enter into definitive agreements reflecting the terms set forth in the Third Party Term Sheet. If the Sandoz Party indicates within such [**] period that it wishes to negotiate and enter into definitive agreements, Momenta and such Sandoz Party shall in good faith negotiate definitive agreements reflecting the terms set forth in the Third Party Term Sheet. If, despite such good faith negotiations, Momenta and the Sandoz Party have not entered into such definitive agreements within [**] after such Sandoz Party's receipt of the Third Party Term Sheet Notice (as such period may be extended by mutual agreement of the Parties), then Momenta shall be free to negotiate and enter into definitive agreements reflecting the terms set forth in the Third Party Term Sheet with the applicable Third Party. Momenta shall not be obligated to reveal to the Sandoz Parties the identity of any Third Party involved in any such transaction.

3.4.6 License to Momenta. Momenta shall have the right to use any and all preclinical, clinical, technical and other relevant data, records, reports, information, materials and technology in its possession or in the possession of the Sandoz Parties (to the extent the Sandoz Parties have the right to transfer the foregoing to Momenta) (including, without limitation, manufacturing technology) that arises from and is used in the Collaborative Program (collectively, "Program Output") in its Development and Commercialization of the Product for any country in the Non-U.S. Territory with respect to which a Sandoz Party has not exercised the Non-U.S. Option prior to the expiration of the Non-U.S. Option Period and for any country in the Non-U.S. Territory with respect to which Momenta and a Sandoz Party have not executed the Non-U.S. Territory Agreement either prior to the expiration of the Initial Non-U.S. Territory Negotiation Period or pursuant to Section 3.4.5. In the event that any item of

Program Output constitutes Sandoz IP, the Sandoz Parties automatically grant to Momenta, upon the expiration of the Non-U.S. Option Period and/or the expiration of the Initial Non-U.S. Territory Negotiation Period, as applicable, a non-exclusive, sublicenseable, royalty-free license under such Sandoz IP to (a) Develop, make, have made, use, sell, offer to sell, lease, import and export the Product in the Field in any country in the Non-U.S. Territory with respect to which a Sandoz Party has not exercised the Non-U.S. Option prior to the expiration of the Non-U.S. Option Period and in any country in the Non-U.S. Territory with respect to which Momenta and a Sandoz Party have not executed the Non-U.S. Territory Agreement either prior to the expiration of the Initial Non-U.S. Territory Negotiation Period or pursuant to Section 3.4.5, and (b) make and have made the Product anywhere in the world for the purpose of sale of the Product in the Field into any country in the Non-U.S. Territory with respect to which a Sandoz Party has not exercised the Non-U.S. Option prior to the expiration of the Non-U.S. Option Period and into any country in the Non-U.S. Territory with respect to which Momenta and a Sandoz Party have not executed the Non-U.S. Territory Agreement either prior to the expiration of the Initial Non-U.S. Territory Negotiation Period or pursuant to Section 3.4.5. Program Output shall expressly exclude, and Momenta shall have no right to use or share with any Third Party, any financial information (other than total per-unit costs of the Product with no breakdown of the components thereof), that was created, generated or compiled pursuant to the Collaborative Program and otherwise pursuant to this Agreement. Nothing in this Section 3.4.6 shall be interpreted or construed to in any way license, authorize or otherwise permit Momenta or any Third Party to use any Program Output or practice any Sandoz IP in any manner that is inconsistent with the Sandoz Parties' rights under this Agreement.

3.5. Equity Investment. Momenta hereby grants to Sandoz a non-exclusive option to invest between U.S.$5,000,000 and U.S.$10,000,000 in a class of preferred stock of Momenta to be substantially equivalent to Momenta's Series B Convertible Preferred Stock, U.S.$0.01 par value per share, at a mutually agreed share price and subject to such obligations and restrictions, and entitled to such rights and preferences, as those currently imposed and bestowed on the holders of Momenta's Series B Convertible Preferred Stock. The exercise of such option shall be subject to the execution of definitive agreements containing the terms and conditions customary in such agreements and the approval thereof by the respective boards of directors of Momenta and Sandoz, and, to the extent applicable, by certain stockholders of Momenta. The option granted by Momenta pursuant to this Section 3.5 shall expire unless such definitive agreements are executed within ninety (90) days after the Effective Date, as such date may be extended by mutual consent of Momenta and Sandoz. In the event of the exercise by Sandoz of its option pursuant to this Section 3.5, Momenta and Sandoz agree to negotiate such definitive agreements in good faith and to use Commercially Reasonable Efforts to obtain all necessary approvals and execute such definitive agreements prior to the expiration of such ninety-day period.

3.6. Sandoz Affiliates. The Sandoz Parties may permit any of their Affiliates to exercise all or any portion of the rights of the Sandoz Parties pursuant to this Article 3 and in

such event, all applicable references to 'Sandoz,' a 'Sandoz Party' or the 'Sandoz Parties' shall be considered references to such Affiliate(s); provided that any such Affiliate(s) agree to be bound by the restrictions and obligations applicable to the Sandoz Parties pursuant to the applicable provisions of this Article 3.

4. FINANCIAL PAYMENTS

4.1. Capped Costs. Subject to the provisions of this Agreement, BCWI shall be responsible for all Development Costs and Sandoz shall be responsible for all Legal Expenses incurred by the Parties in performing their obligations under this Agreement, up to a maximum of an aggregate of such Development Costs and Legal Expenses of U.S.$[**] (the "Cost Cap"). Within thirty (30) days after the end of each Quarter during this Agreement, the Sandoz Parties shall provide to Momenta a written report documenting any Capped Costs incurred by the Sandoz Parties during such just-ended Quarter. Within thirty (30) days after the end of each Quarter during this Agreement, Momenta shall provide to the Sandoz Parties an invoice (together with supporting documentation) for any Capped Costs incurred by Momenta during such just-ended Quarter (which, with respect to the first Quarter under this Agreement, shall include the Pre-Existing Costs), and payments will be due to be made to Momenta by the applicable Sandoz Party(ies) for any Capped Costs incurred by Momenta within forty-five (45) days of receipt of such invoice. Capped Costs shall be incurred by the Parties according to the Annual Collaboration Plan. Any material deviation from the Annual Collaboration Plan shall immediately be reported to the Joint Steering Committee.

4.2. FTE Funding. Momenta will provide [**] FTEs during the [**] period commencing October 1, 2003 under this Agreement and [**] FTEs during the following [**] period under this Agreement, devoted exclusively to efforts on behalf and in furtherance of the Collaborative Program. As compensation for the provision of such FTEs, BCWI shall pay Momenta, effective as of October 1, 2003, at the FTE Rate. Additional FTEs, as mutually agreed to in the applicable Annual Collaboration Plan, will be provided by Momenta, and paid for by BCWI (subject to the provisions of Section 4.11.8) at the FTE Rate ("Additional FTE's"). Within thirty (30) days after the end of each Quarter during such time periods, Momenta shall provide to BCWI a report of the number of FTEs actually devoted by Momenta to the Collaborative Program during such just-ended Quarter and payments will be due by BCWI within forty-five (45) days after receipt of such report, based on the number of FTEs actually committed by Momenta to the Collaborative Program during such Quarter at the FTE Rate, *pro rata* for such actual number of FTEs. Momenta shall track the number of FTEs devoted to the Collaborative Program on a monthly basis in accordance with Momenta's standard record-keeping practices (including without limitation the use of at a minimum monthly timesheets) (the "FTE Records").

4.3. Excess Costs. Subject to the provisions of Sections 4.11.8 and 11.5 and Schedule 4.3, Sandoz shall bear responsibility for all Excess Costs. Within fifteen (15) days after the end of each Quarter during this Agreement, Momenta shall provide to Sandoz an invoice (together with supporting documentation) for any Excess Costs paid by Momenta during such just-ended Quarter, and payments will be due to be made to Momenta by Sandoz for any Excess Costs paid by Momenta within forty-five (45) days of receipt of such invoice.

4.4. Commercialization Costs. Sandoz shall be responsible for all Commercialization Costs. Momenta shall bear no responsibility for the Commercialization Costs.

4.5. U.S. Profit Interest. In the event that, at the time of U.S. Launch, there [**] (the "[**] Period"), then, subject to the provisions of Section 4.9, for each Post-Launch Quarter during such [**] Period during which Sandoz, its Affiliates or distributors is selling the Product in the U.S. Territory, Sandoz shall pay Momenta an amount computed by multiplying forty-five percent (45%) times the Profits in the U.S. Territory during such Post-Launch Quarter (the "Profit Interest"), which shall be adjusted pursuant to Schedule 4.3. The [**] Period shall automatically terminate upon the existence of [**] the U.S. Territory and the provisions of this Section 4.5 shall not apply thereafter.

4.6. U.S. Post-[**] Royalty.

4.6.1 Upon termination of the [**] Period, Section 4.5 shall no longer apply. Subject to the provisions of Section 4.8, if such termination occurs after the [**] anniversary of the U.S. Launch, then, following such termination (subject to the provisions of Section 4.9), for each Post-Launch Quarter during which Sandoz, its Affiliates or distributors is selling the Product in the U.S. Territory (the "[**] Period"), Sandoz shall pay Momenta a royalty (the "[**] Royalty") as a percentage of Net Sales of the Product in the U.S. Territory to be computed according to the following table, by multiplying Net Sales in the U.S. Territory for such Post-Launch Quarter times the applicable percentage listed in the following table:

Net Sales in U.S. Territory During a Post-Launch Year	**Royalty Rate**
First U.S.$[**] Million in Net Sales in the U.S. Territory	10%
Over U.S.$[**] Million in Net Sales in the U.S. Territory	12%

4.6.2 The amounts payable under Section 4.6.1 shall be adjusted pursuant to Schedule 4.3.

4.7. U.S. [**] Royalty.

4.7.1 In the event that (a) at the time of U.S. Launch there are [**] or (b) termination of the [**] Period occurs on or before the [**] anniversary of the U.S. Launch (in which case, upon such termination the provisions of Section 4.5 shall no longer apply), then, subject to the provisions of Sections 4.8 and 4.9, for each Post-Launch Quarter during which Sandoz, its Affiliates or distributors is selling the Product in the U.S. Territory (the "[**] Period"), Sandoz shall pay Momenta a royalty (the "[**] Royalty") as a percentage of Net Sales of the Product in the

U.S. Territory to be computed according to the following table, by multiplying Net Sales in the U.S. Territory for such Post-Launch Quarter times the applicable percentage listed in the table:

Net Sales in U.S. Territory During a Post-Launch Year	Royalty Rate
First U.S.$[**] Million in Net Sales in the U.S. Territory	[**]%
Over U.S.$[**] Million in Net Sales in the U.S. Territory	[**]%

4.7.2 The amounts payable under Section 4.7.1 shall be adjusted pursuant to Schedule 4.3.

4.8. Aventis [**].

4.8.1 If the [**] Period (i) terminates because there is [**], or (ii) never existed as a result of [**]; then (subject to the provisions of Section 4.9) thereafter until such time as there is [**] (the "Aventis [**]"), at which time the provisions of Section 4.6 or Section 4.7, as applicable, shall govern, Sandoz shall pay the Post-[**] Royalty during each Post-Launch Year (or portion thereof) until such time as the total Profits for the Product in the U.S. Territory for such Post-Launch Year (or portion thereof) equal the Aventis [**], and thereafter, solely with respect to any Profits exceeding the Aventis [**], during the remainder of such Post-Launch Year, Sandoz shall pay Momenta the Profit Interest with respect to such excess. The Aventis [**] shall automatically terminate upon the existence of [**] in the U.S. Territory and the provisions of this Section 4.8 shall not apply thereafter.

4.8.2 The amounts payable under Section 4.8.1 shall be adjusted pursuant to Schedule 4.3.

4.9. Allocation Between Periods. In the event that a termination of the [**] and/or the Aventis [**] falls on a day other than the first day of a Post-Launch Quarter, the Profit Interest and Post-[**] Royalty or [**] Royalty, as the case may be, for such Post-Launch Quarter shall be paid for such Post-Launch Quarter based upon the actual Net Sales made during such Post-Launch Quarter under the [**] Period, the Aventis [**] and/or the Post-[**] Royalty Period or [**] Royalty Period, as the case may be.

4.10. Milestone Payments.

4.10.1 Regulatory Milestone Payment. The Sandoz Parties shall pay Momenta a one-time non-creditable, non-refundable milestone payment equal to Five Million Dollars (U.S.$5,000,000) ("Regulatory Milestone Payment") on the earlier of (a) Final Legal Clearance or (b) U.S. Launch; provided, however, that the Regulatory Milestone Payment is payable only if (i) Sandoz receives ANDA Final Approval

for an ANDA filed by Sandoz or any of its Affiliates for the Product before any Third Party (other than [**]) receives ANDA Final Approval for an ANDA filed by such Third Party for a Lovenox®-Equivalent Product, and (ii) (A) if U.S. Launch occurs prior to Final Legal Clearance, there is [**] in the U.S. Territory at the time of U.S. Launch, or (B) if Final Legal Clearance occurs prior to U.S. Launch, no Third Party (other than [**]) has received ANDA Final Approval for an ANDA filed by such Third Party for a Lovenox®-Equivalent Product at the time of Final Legal Clearance.

4.10.2 Commercial Milestone Payments.

a. The Sandoz Parties shall pay Momenta the following milestone payments (the "Full Milestone Payments") (as shall be adjusted pursuant to Schedule 4.3, the "Commercial Milestone Payments"); provided that each such milestone payment shall be payable only if (i) Sandoz has sold the Product during the twelve (12) months immediately preceding the events described below, or Sandoz's failure to sell the Product during such period is a breach of this Agreement, and (ii) as of each anniversary described below, there is [**] in the U.S. Territory:

Milestone Event	Amount of Milestone	
First anniversary of U.S. Launch	U.S.$	10,000,000
[**] anniversary of U.S. Launch	U.S.$	[**]
[**] anniversary of U.S. Launch	U.S.$	[**]
[**] anniversary of U.S. Launch	U.S.$	[**]
[**] anniversary of U.S. Launch	U.S.$	[**]

b. Each Commercial Milestone Payment shall be made within forty-five (45) days after the end of the applicable Post-Launch Quarter in which the Milestone Event referenced in the above table occurs; provided, however, that if any Milestone Event occurs prior to Final Legal Clearance, the applicable Commercial Milestone Payment for such Milestone Event shall be made within forty-five (45) days after the end of the Post-Launch Quarter in which Final Legal Clearance occurs. For purposes of this Agreement, each such Post-Launch Quarter when a Commercial Milestone Payment is actually made shall be a "Milestone Payment Quarter". For example, if Final Legal Clearance occurs midway between the [**] and [**] anniversary of U.S. Launch, the first two (2) Commercial Milestone Payments shall be due 45 days after the end of the Post-Launch Quarter in which Final Legal Clearance occurs. For the avoidance of doubt, if Final Legal Clearance does not occur during the Term, no Commercial Milestone Payment(s) shall be due to Momenta.

4.11. Payment/Accounting.

4.11.1 Time and Manner of Payment of Royalties. The Sandoz Parties (and/or Momenta in the event Section 11.6.3 applies) shall report the amount of Product sold in each Post-Launch Quarter, the gross amount invoiced, the deductions used in the calculation of Net Sales, the applicable Manufacturing Costs and the resulting calculation of Profit Interest or royalties due to Momenta (or the Sandoz Parties, as applicable), within forty-five (45) days after the end of such Post-Launch Quarter. With each such report, the Sandoz Parties (or Momenta, as applicable) shall pay the amount of Profit Interest or royalties due. If no Profit Interest or royalties are due, the report shall so state. Reports shall provide a reconciliation showing the amount due.

4.11.2 Computation. All payments due shall be payable in United States dollars. Such payments shall be without deduction of exchange, collection, or other charges, and, specifically, without deduction of withholding or similar taxes or other government imposed fees or taxes, except as otherwise permitted in the definition of "Net Sales" or by this Section 4.11.

4.11.3 Interest. Interest shall be payable on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of (a) two percentage points above the prime rate of interest, as reported by The Wall Street Journal for the applicable period, or (b) the highest rate permitted by applicable law, in each case calculated on the number of days such payments are paid after the date they are due.

4.11.4 Record Keeping. The Sandoz Parties and Momenta shall keep, and shall require their Affiliates, distributors, licensees and sublicensees to keep, accurate and complete accounting records of the Products sold under this Agreement ("Product Records") appropriate to determine the amount of Profit Interest or royalties due hereunder and to support the reports made pursuant to Section 4.11.1. Such records shall be retained for at least five (5) years following a given reporting period.

4.11.5 Sandoz Audit. Upon sixty (60) days' prior written notice, the Sandoz Parties shall permit their books and records of Capped Costs, Excess Costs and Product Records to be examined for a particular calendar year, no more than once annually, during normal business hours, by an independent auditor appointed by Momenta and reasonably acceptable to the Sandoz Parties, and at Momenta's expense, to the extent necessary to verify the accuracy of the Profit Interest and royalty reports delivered by the Sandoz Parties under this Agreement. Any information received as a result of such inspection shall be maintained as the Sandoz Parties' Confidential Information.

4.11.6 Momenta Audit. Upon sixty (60) days' prior written notice, Momenta will permit its books and records of Capped Costs, Excess Costs, the FTE Records and

Product Records to be examined for a particular calendar year, no more than once annually, during normal business hours, by an independent auditor appointed by Sandoz (on behalf of itself and BCWI) and reasonably acceptable to Momenta, and at Sandoz's expense, to the extent necessary to verify the accuracy of the invoices and royalty reports delivered by Momenta under this Agreement. Any information received as a result of such inspection shall be maintained as Momenta's Confidential Information.

4.11.7 Underpayment/Overpayment and Payment Disputes. In the event an examining auditor specified in Sections 4.11.5 or 4.11.6 concludes that an underpayment or overpayment was made, the auditor will specify such in a written report along with the information on which such conclusion is based. This report will be shared promptly with the audited Party. The amount of any such underpayment or the reimbursement of any such overpayment shall be due and payable by the audited Party within forty-five (45) days of the date of such report, provided that if a Party disputes the conclusion of the auditor, the Parties will resolve the dispute according to Article 13. If the underpayment by the audited Party or the overpayment by the auditing Party differs by greater than five percent (5%) from the amount that was otherwise due, the audited Party shall pay all of the costs of such review, together with interest calculated on the amount of such underpayment or overpayment in the manner provided in Section 4.11.3.

4.11.8 Relationship Between the Sandoz Parties. As between Sandoz and BCWI, (a) BCWI shall bear responsibility for all Development Costs to the extent such Development Costs are part of Capped Costs and for FTE costs for the first fifteen (15) FTEs in accordance with Section 4.2; (b) Sandoz shall bear responsibility for all payments under Sections 4.3, 4.4, 4.5, 4.6, 4.7 and 4.8, unless Sandoz otherwise makes arrangements with BCWI for any such payments; and (c) the Sandoz Parties shall bear responsibility for all payments under Section 4.10. Sandoz and BCWI are permitted to enter into an agreement between themselves pursuant to which each Sandoz Party shall bear its portion of the Profit Interest and royalties due to Momenta pursuant to this Agreement and for payment of Development Costs that are part of Excess Costs and for Additional FTEs. Sandoz shall guarantee all obligations of BCWI under this Agreement, other than those obligations guaranteed by Sandoz GmbH, as set forth on the signature page of this Agreement.

4.12. True-Up. Notwithstanding any other provision of this Agreement, the Parties agree that for a two-year period after the end of the Term, the Sandoz Parties shall submit to Momenta, on a quarterly basis within forty-five (45) days following the close of each Quarter, a schedule showing any adjustment to the calculations of the Profits from the Product and Net Sales, and the resulting adjustment to payments made to Momenta hereunder, which occurred in such Quarter, and the Party owing any amounts pursuant to such reconciliation shall, within forty-five (45) days of the receipt of such reconciliation, submit payment to the other Party.

5. JOINT DEVELOPMENT AND COMMERCIALIZATION

5.1. Joint Collaboration. Sandoz and Momenta, and, to the extent appropriate, BCWI, shall jointly collaborate in the Development and Commercialization of the Product and the Legal Activities, using Commercially Reasonable Efforts to Develop the Product, to achieve Legal Clearance, to bring the Product to the market in the U.S. Territory within a commercially reasonable time period (subject to the provisions of Section 6.2.1) and to Commercialize the Product in the U.S. Territory. Sandoz shall be responsible for ensuring that representatives of BCWI participate in the Development and Commercialization activities and the Legal Activities as appropriate.

5.2. Joint Project Team. The Development and Commercialization activities and Legal Activities shall be conducted and managed on a day-to-day basis through a Joint Project Team ("Joint Project Team" or "JPT"). Momenta and Sandoz shall each appoint one (1) Project Leader promptly following the Effective Date and may change its Project Leader at any time by giving written notice to the other. The JPT shall consist of three (3) (or such other mutually agreed number) representatives from each of Sandoz and Momenta (including each Party's then-current Project Leader), which representatives shall be directly involved with and responsible for Development and Commercialization activities and Legal Activities. Promptly after the Effective Date, Momenta and Sandoz shall each appoint its representatives to the JPT. Momenta and Sandoz may each change its JPT representatives at any time by giving written notice to the other. The JPT shall meet within thirty (30) days after the Effective Date and, thereafter, at least quarterly during the course of the Collaborative Program. Additional representatives of a Party may attend meetings of the JPT on an *ad hoc* invited basis as appropriate.

5.3. JPT Responsibilities. Except as provided in Sections 5.10, 6.1 and 6.2.1, the JPT shall be responsible for: (a) directing all day-to-day aspects of the Development and Commercialization of, and the Legal Activities with respect to, the Product; (b) preparing and submitting to the Joint Steering Committee ("Joint Steering Committee" or "JSC") an Annual Collaboration Plan for each Contract Year; (c) discussing and resolving ongoing issues; and (d) periodically reporting to the JSC and referring any disputes not resolved by the JPT to the JSC for resolution. The JPT shall only act unanimously and each Party, acting through its representatives, shall have one vote on the JPT. Within thirty (30) days after each meeting, the Project Leaders will jointly provide the JSC with a written report describing, in reasonable detail, the status of the Collaborative Program and the Development and Commercialization of, and Legal Activities with respect to, the Product, including, without limitation, a summary of the results and progress to date, the status of the then-current budget in the Annual Collaboration Plan (actuals vs. estimates), project timelines, critical path issues and any other issues requiring resolution, proposed solutions to such issues, and the agreed resolution of previously reported issues.

5.4. Joint Steering Committee. The JSC shall consist of six (6) members, three (3) representatives from each of Sandoz and Momenta, each of whom shall have experience and seniority sufficient to enable him or her to make decisions on behalf of the Party he or she represents. Promptly after the Effective Date, Momenta and Sandoz shall each appoint its representatives to the JSC. Momenta and Sandoz may each change its JSC representatives at any time by giving written notice to the other.

5.5. JSC Administration. The JSC shall appoint a chairperson from among its members, which shall rotate annually between the representatives from Sandoz and the representatives from Momenta. The chairperson shall be responsible for calling meetings of the JSC and for leading the meetings. A JSC member of the Party hosting a meeting of the JSC (or someone designated by the JSC) shall serve as secretary of that meeting. The secretary of the meeting shall prepare and distribute to all members of the JSC draft minutes of the meeting within thirty (30) days following the meeting to allow adequate review and comment. Such minutes shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, decisions or determinations approved by the JSC. Minutes of each JSC meeting shall be approved or disapproved, and revised as necessary, at the next meeting. Final minutes of each meeting shall be distributed to the members of the JSC by the chairperson.

5.6. JSC Meetings. The location of meetings of the JSC shall alternate between Sandoz's principal place of business and Momenta's principal place of business, or as otherwise agreed by the Parties. The JSC may also meet by means of a telephone conference call or videoconference. Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JSC. If a representative of a Party is unable to attend a meeting, such Party may designate an alternate to attend such meeting in place of the absent representative. In addition, each of Momenta and Sandoz may, at its discretion, invite non-voting employees, and, with the consent of Sandoz and Momenta, respectively, consultants or scientific advisors, to attend the meetings of the JSC to, among other things, review and discuss the Collaborative Program and its results. Either Momenta or Sandoz may convene a special meeting of the JSC for the purpose of resolving disputes.

5.7. JSC Responsibilities. Except as provided in Sections 5.10, 6.1 and 6.2.1, the JSC shall be responsible for: (a) overseeing the Development and Commercialization activities and Legal Activities under the Collaborative Program (including, without limitation, (i) determining the strategy to achieve Legal Clearance, such as the decision regarding which Locked Manufacturing Process to employ, (ii) determining the enforcement strategy with respect to the Joint Collaboration IP, and (iii) determining the patent prosecution and enforcement strategy with respect to those Product-Specific Patent Rights relevant to the exercise by Sandoz of the licenses granted in Section 2.1); (b) providing overall guidance to the JPT; (c) approving the Annual Collaboration Plan or any changes thereto, including without limitation, the budget contained therein pursuant to Section 5.8 and any changes thereto; (d) reviewing progress toward milestones in the Annual Collaboration Plan; (e) attempting to resolve disputes; and (f) performing such other tasks and undertaking such other responsibilities as are set forth in this Agreement. The JSC shall only act unanimously and each of Momenta and Sandoz, acting through its representatives, shall have one vote on the JSC. The JSC shall meet within thirty (30) days after the Effective Date and, thereafter, at least quarterly during the course of the Collaborative Program. Within thirty (30) days after each meeting, the persons appointed by the JSC will provide Sandoz (on behalf of Sandoz and BCWI) and Momenta with a written report describing, in reasonable detail, the status of the Collaborative Program and the Development and Commercialization of, and Legal Activities with respect to, the Product, a summary of the results and progress to date, any issues requiring resolution, and the agreed resolution of previously reported issues. Disputes shall be resolved pursuant to Article 13.

5.8. Annual Collaboration Plan. The Parties shall undertake the Collaborative Program in accordance with the Annual Collaboration Plans. The JPT shall prepare the Annual Collaboration Plan (a) for the First Contract Year within thirty (30) days after the Effective Date, (b) for the Second Contract Year at least sixty (60) days prior to the commencement of such Contract Year, and (c) for the Third Contract Year and subsequent Contract Years at least ninety (90) days prior to the commencement of such Contract Year. The JSC shall review and approve the Annual Collaboration Plan (i) for the First Contract Year within forty-five (45) days after the Effective Date, (ii) for the Second Contract Year at least thirty (30) days prior to the commencement of such Contract Year, and (iii) for the Third Contract Year and subsequent Contract Years at least sixty (60) days prior to the commencement of such Contract Year. The JPT shall prepare, and the JSC shall review and approve, updates and amendments, as appropriate, to the then-current Annual Collaboration Plan during the course of the applicable Contract Year. Each Annual Collaboration Plan shall be consistent with the other terms and conditions of this Agreement. Each Annual Collaboration Plan shall specify, among other things, (A) specific objectives of the Collaborative Program during the applicable Contract Year, (B) specific activities to be performed by each Party, or by Third Parties, in support of the Collaborative Program during the applicable Contract Year, and (C) a budget reflecting the resources (including FTEs) to be assigned and amounts expended by each Party in support of the Collaborative Program. In particular, to support the Development and Commercialization of, and Legal Activities with respect to, the Product, the Annual Collaboration Plan shall specify the activities to be performed by each Party, or by Third Parties, and the related resources (including FTEs) to be assigned and the strategic marketing plan for the Product in the U.S. Territory. In preparing the initial Annual Collaboration Plan, the JPT shall assign specific activities to the relevant Party(ies). While all activities will be considered joint activities within the collaboration, the JPT shall assign specific activities to the relevant Party(ies) to execute. Schedule 5.8 provides a preliminary list of activities to be included in the Annual Collaboration Plan, along with a preliminary assignment of the Party(ies) responsible for each activity. The Annual Collaboration Plan, to be approved by the JSC, will include a complete list of activities and the assignment of the relevant Party(ies) for each such activity. While a given Party may be assigned the lead responsibility for an activity, it will be the responsibility of such Party to achieve cross-company alignment on the strategy and the plans to complete the activity consistent with the integrated strategy as defined in the Annual Collaboration Plan.

5.9. Compliance with Laws. Each Party agrees to use Commercially Reasonable Efforts to carry out all work assigned to such Party in the Annual Collaboration Plan and its other obligations under this Agreement in material compliance with all applicable federal, state or local laws, regulations and guidelines governing the conduct of such work, including, without limitation, (a) the FD&C Act and any applicable implementing regulations; (b) cGMPs; (c) all other applicable FDA guidelines; (d) all other applicable laws, including all applicable U.S., federal, state, foreign and local environmental, health and safety laws in effect at the time and place of manufacture of a Product; and (e) all applicable export and import control laws.

5.10. Legal Clearance. Sandoz shall have sole responsibility to make decisions with respect to Legal Clearance (except with respect to the determination of whether Legal Clearance has occurred, which shall be determined in accordance with the definitions herein of District

Court Legal Clearance and Final Legal Clearance); provided that such decisions are generally consistent with the strategy set therefor by the JSC, and subject to the provisions of Section 13.2.

6. COMMERCIALIZATION BY SANDOZ

6.1. Review and Oversight. Other than with respect to Section 6.2.1, which shall be in the sole discretion of Sandoz, all responsibilities of the Parties with respect to Commercialization of the Product shall be subject to the oversight and review of the Joint Project Team and the Joint Steering Committee as set forth in Article 5. Notwithstanding Section 5.8 or any other provision of this Agreement, Sandoz and its Affiliates (or, with respect to Section 11.6.1, Momenta, its Affiliates and sublicensees) shall have the sole discretion and exclusive authority to set the prices for the Product sold to Third Parties. The Parties shall agree upon the trademark to be used for the Product, which shall not include any trademark or tradename or a part thereof that uses the name "Novartis" or "Sandoz" or a derivative thereof or any other trademark or part or derivative thereof that is the name or derivative of a name of any other Sandoz Affiliate.

6.2. Pre Final Legal Clearance Launch.

6.2.1 Notwithstanding any other provision in this Agreement, the Parties agree that, if ANDA Final Approval for an ANDA filed by Sandoz or any of its Affiliates for the Product has been obtained and a District Court Decision has been obtained but Final Legal Clearance has not yet been obtained, Sandoz may, in its sole discretion, decide whether to proceed with U.S. Launch, or to defer U.S. Launch until Final Legal Clearance. Upon deciding to proceed with Pre Final Legal Clearance Launch, Sandoz shall promptly notify Momenta of such decision and shall use Commercially Reasonable Efforts to Commercialize the Product.

6.2.2 Notwithstanding anything else herein to the contrary, the Parties agree that, consistent with the provisions of Section 12.1(c), Sandoz shall bear, and Momenta shall not be responsible for, any damages of Aventis in the event that Sandoz or its Affiliates are held liable for [**] under Patent Litigation, other than with respect to Momenta's responsibility for a portion of Settlement Costs pursuant to the provisions of Section 4.3.

7. REGULATORY MATTERS

7.1. Review and Oversight. All responsibilities under this Article 7 shall be subject to the review and oversight of the Joint Project Team and the Joint Steering Committee as set forth in Article 5.

7.2. ANDA Filing. Sandoz shall file an ANDA for the Product in accordance with the Annual Collaboration Plans. The ANDA for the Product shall be filed with the FDA by Sandoz under Sandoz's name. If the ANDA for the Product includes a certification pursuant to 21 U.S.C. 355(b)(2)(iv) or 355(j)(2)(A)(vii), Sandoz shall also provide to the applicable Aventis Person notice, as required by 21 USC § 355(b)(3) or 21 U.S.C. § 355(j)(2)(B), respectively.

7.3. Ownership Of The ANDAs. Sandoz shall own all ANDAs for the Product and all rights in all data supporting the ANDAs for the Product.

7.4. ANDA Responsibility. The JSC shall determine the responsibilities of each Party with respect to the preparation of the ANDAs for the Product and related activities.

7.5. Regulatory Interaction. The JSC shall determine the responsibilities of each Party with respect to interactions with the FDA with respect to the Product; provided, however, that Sandoz shall interact with the FDA with respect to adverse event reporting obligations.

8. INTELLECTUAL PROPERTY

8.1. Ownership.

8.1.1 Single Ownership. As between Momenta and the Sandoz Parties, the Sandoz Parties shall own all Sandoz IP and Momenta shall own all Momenta IP. Momenta hereby assigns to the Sandoz Parties all right, title and interest in and to any Improvements to Sandoz Know-How or Improvements to Sandoz Collaboration Know-How that are conceived and reduced to practice or developed solely by Momenta or its Affiliates, or jointly by a Sandoz Party or its Affiliates, on the one hand, and by Momenta or its Affiliates, on the other hand, during, and in the conduct of, the Collaborative Program ("Momenta Assigned Improvements"). Each of Sandoz and BCWI hereby assigns to Momenta all right, title and interest in and to any Improvements to Momenta Know-How or Improvements to Momenta Collaboration Know-How that are conceived and reduced to practice or developed solely by Sandoz or BCWI, or jointly by Sandoz or BCWI, on the one hand, and by Momenta or its Affiliates, on the other hand, during, and in the conduct of, the Collaborative Program ("Sandoz Assigned Improvements"). The assigning Party shall execute all documents necessary to effectuate this Section 8.1.1. Notwithstanding anything to the contrary herein, BCWI, with respect to the Sandoz IP, and Momenta, with respect to the Momenta IP, shall have the right to assign the Sandoz IP, in the case of BCWI, or the Momenta IP, in the case of Momenta, to its respective Affiliates, without the consent of the other Party, or to Third Parties, with the consent of the other Party, such consent not to be unreasonably withheld, so long as any such assignment pursuant to this sentence is subject to the licenses granted pursuant to this Agreement and is otherwise consistent with this Agreement.

8.1.2 Momenta hereby grants to Sandoz and BCWI an irrevocable, perpetual, non-exclusive, royalty-free, sublicensable license to practice the Sandoz Assigned Improvements outside of the Field. Each Sandoz Party hereby grants to Momenta an irrevocable, perpetual, non-exclusive, royalty-free, sublicensable license to practice the Momenta Assigned Improvements outside of the Field.

8.1.3 Joint Ownership. All Joint Collaboration IP shall be owned jointly on the basis of an undivided one-half interest by BCWI and Momenta. Notwithstanding anything to the contrary herein, BCWI and Momenta shall each have the right to

sell, license or otherwise transfer such Joint Collaboration IP to its Affiliates or any Third Party without the consent of the other Party so long as such sale, license or transfer is subject to the licenses granted pursuant to this Agreement and is otherwise consistent with this Agreement.

8.1.4 Inventorship. Inventorship shall be determined by the Parties in good faith in accordance with relevant patent laws. In the event of a dispute regarding inventorship or the ownership of Collaboration Know-How that the Parties are unable to resolve, mutually acceptable outside patent counsel not regularly employed by any Party or their Affiliates shall be retained to resolve such dispute.

8.1.5 Policies. In order to protect the Parties' Patent Rights under United States laws in any inventions conceived or reduced to practice during or as a result of the Collaborative Program, each Party agrees to maintain a policy that requires its employees, individual contractors, consultants and agents to record and maintain all data and information developed in the course of the Collaborative Program in such a manner as to enable the Parties to use such records to establish the earliest date of conception, invention and/or to document diligent reduction to practice. At a minimum, the policy shall require such individuals to record all inventions generated by them in standard laboratory notebooks that are dated and corroborated by non-inventors on a regular, contemporaneous basis.

8.2. Patent Prosecution.

8.2.1 Momenta Patent Rights. Subject to any contractual obligations to, or restrictions imposed by, Momenta's Third Party licensors, Momenta shall use Commercially Reasonable Efforts to timely prepare, file, prosecute and maintain, at its expense, Momenta Patent Rights and Momenta Collaboration Patent Rights (in each case, other than any Product-Specific Patent Rights relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1) in the United States and throughout the world.

8.2.2 Sandoz Patent Rights. Subject to any contractual obligations to, or restrictions imposed by, the Sandoz Parties' Third Party licensors, the Sandoz Parties shall use Commercially Reasonable Efforts to timely prepare, file, prosecute and maintain, at its expense, Sandoz Patent Rights and Sandoz Collaboration Patent Rights (in each case, other than any Product-Specific Patent Rights relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1) in the United States and throughout the world.

8.2.3 Joint Patent Rights. Subject to any contractual obligations to, or restrictions imposed by, the Parties' Third Party licensors, the JSC shall make all decisions regarding whether and how to file, prosecute and maintain any Joint Collaboration Patent Rights (other than any Product-Specific Patent Rights), including without limitation, the ability of Momenta or a Sandoz Party, as the case may be, to assume control of the filing, prosecution or maintenance of such Joint Collaboration Patent Rights in the name of the Sandoz Parties or Momenta,

respectively, if the Sandoz Parties or Momenta, respectively, decline to file, prosecute or maintain such Joint Collaboration Patent Rights, elect to allow any such Joint Collaboration Patent Rights to lapse or elect to abandon any such Joint Collaboration Patent Rights before all appeals within the respective patent office have been exhausted; provided, however, that, in the event of a dispute with respect to such decisions that the Parties are unable to resolve, mutually acceptable outside patent counsel not regularly employed by any Party or their Affiliates shall be retained to resolve such dispute.

8.2.4 Product-Specific Patent Rights. Subject to any contractual obligations to, or restrictions imposed by, the Parties' Third Party licensors, the JSC shall make all decisions regarding whether and how to file, prosecute and maintain any Product-Specific Patent Rights relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1, including without limitation, the ability of Momenta or a Sandoz Party, as the case may be, to assume control of the filing, prosecution or maintenance of such Product-Specific Patent Rights of the Sandoz Parties or Momenta, respectively, in the name of the Sandoz Parties or Momenta, respectively, if the Sandoz Parties or Momenta, respectively, decline to file, prosecute or maintain such Product-Specific Patent Rights, elect to allow any such Product-Specific Patent Right to lapse or elect to abandon any such Product-Specific Patent Right before all appeals within the respective patent office have been exhausted; provided, however, that, in the event of a dispute with respect to such decisions that the Parties are unable to resolve, mutually acceptable outside patent counsel not regularly employed by any Party or their Affiliates shall be retained to resolve such dispute.

8.2.5 Cooperation and Assistance. The Parties agree to cooperate with each other and render all reasonable assistance as may be necessary to support any patent application filed by another Party under this Section 8.2, including, but not limited to, consulting and coordinating with each other on any such patent filing activities to ensure that any Patent Rights or Confidential Information are not unduly compromised.

8.3. Participation of other Persons.

8.3.1 Each of the Sandoz Parties and Momenta shall be responsible for executing an appropriate agreement with each employee, individual contractor, consultant or agent (including, for purposes of clarity, individuals who regularly work for Affiliates of the Sandoz Parties or Momenta) working on their respective behalves on the Collaborative Program, including a provision requiring such employee, individual contractor, consultant or agent to assign to a Sandoz Party or Momenta, respectively, all Know-How and Patent Rights which he or she develops or conceives and/or reduces to practice during his or her work on the Collaborative Program so that such Know-How and Patent Rights are Controlled by such Sandoz Party or Momenta, respectively.

8.3.2 In the event that a Sandoz Party elects to contribute any Know-How of an Affiliate of such Sandoz Party and any associated Patent Rights to the Collaborative Program, such Sandoz Party shall be responsible for executing an appropriate agreement with such Affiliate requiring such Affiliate to assign to such Sandoz Party, or to exclusively license to such Sandoz Party in the Field, all such Know-How and/or Patent Rights so that such Know-How and/or Patent Rights are Controlled by such Sandoz Party. For purposes of clarity, the decision whether or not to contribute any such Know-How and associated Patent Rights for use in the Collaborative Program shall be in the sole discretion of such Sandoz Party.

8.3.3 Except as the Parties may otherwise agree in writing, each of the Sandoz Parties and Momenta shall be responsible for executing an appropriate agreement with each Affiliate or Third Party contracting entity working on their respective behalves on the Collaborative Program, including a provision requiring such entity to assign to such Sandoz Party or Momenta, respectively, or exclusively license to such Sandoz Party or Momenta, respectively, in the Field, all Know-How and Patent Rights with respect to the Field which such entity develops or conceives and/or reduces to practice during its work on the Collaborative Program so that such Know-How and Patent Rights are Controlled by such Sandoz Party or Momenta, respectively.

8.3.4 Each Party shall use Commercially Reasonable Efforts to enforce the terms of their respective agreements described in Sections 8.3.1, 8.3.2 and 8.3.3.

8.4. Enforcement of Non-Product-Specific Patent Rights.

8.4.1 Initial Rights. Subject to any contractual obligations to, or restrictions imposed by, its Third Party licensors, the Owning Party shall have the initial right, but not the obligation, to institute an infringement action or take other appropriate action that it believes is reasonably required to protect the Owning Party's IP (other than any Product-Specific Patent Rights relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1) from infringement in the Field, when, from its own knowledge or upon notice from another Party, the Owning Party becomes aware of the reasonable probability that such infringement exists in the Field. With respect to infringement in the Field in the U.S. Territory, the Non-Owning Party may at any time join in any infringement action brought by the Owning Party and may be represented by counsel of its choice, but control of such action shall remain with the Owning Party. Each other Party shall join in any infringement action as a party at the Owning Party's request in the event that an adverse party asserts, or the Owning Party determines in good faith, that a court lacks jurisdiction based on such other Party's absence as a party in such suit.

8.4.2 Step-In Rights. Subject to any contractual obligations to, or restrictions imposed by, the Owning Party's Third Party licensors, in the event that the Owning Party shall not, within six (6) months of written notice from another Party

of a suspected infringement of the Owning Party's IP (other than any Product-Specific Patent Rights relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1) by a Third Party making, using, selling, offering to sell or importing a product in the Field in the U.S. Territory, commence and vigorously pursue an action to enjoin such infringement, the Non-Owning Party shall be entitled, at its expense, to commence the action in its name; provided, however, that the Non-Owning Party shall consult with the Owning Party with respect to such action and shall give due consideration to the Owning Party's advice and the Owning Party's intellectual property protection strategy. The Owning Party shall join in any infringement action as a party, at the request of the Non-Owning Party, in the event that the court rules or other laws then applicable shall require the joinder of the Owning Party as the owner of the Owning Party's IP (other than any Product-Specific Patent Rights relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1) for purposes of prosecuting such infringement action, but shall have no obligation to actively participate or incur expenses beyond the minimum level necessary to appear for the purpose of sustaining jurisdiction.

8.4.3 Costs. Each Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings described in this Section 8.4, including, without limitation, the fees and expenses of such Party's counsel.

8.4.4 Recoveries. Subject to any contractual obligations to, or restrictions imposed by, the Owning Party's Third Party licensors, any recovery obtained by a Party(ies) as a result of any proceeding described in this Section 8.4 or from any counterclaim or similar claim asserted in a proceeding described in Section 8.5, by settlement or otherwise, shall be applied as follows:

a. First, to reimburse each Party for all litigation costs in connection with such proceeding paid by that Party (on a pro rata basis based on each Party's respective litigation costs, to the extent the recovery was less than all such litigation costs); and

b. Second, the remainder of the recovery shall be paid [**] percent ([**]%) to the Sandoz Parties and [**] ([**]%) to Momenta.

8.4.5 Cooperation; Settlements. In the event that any Party takes action pursuant to this Section 8.4, each other Party shall cooperate with the Party so acting to the extent reasonably possible, including the joining of suit as required by this Agreement or as otherwise desirable. No Party participating in such suit shall settle or compromise any claim or proceeding relating to another Party's Patent Rights or Know-How without obtaining the prior written consent of such other Party, such consent not to be unreasonably withheld, it being understood that the consent of a Third Party licensor of such other Party may also be required in order to settle or compromise any claim or proceeding relating to such Party's Patent Rights or Know-How.

8.5. Claimed Infringement. In the event that a Party becomes aware that the manufacture, use, sale, offer to sell or importation of the Product infringes, or is likely to or is alleged to infringe, the Patent Rights or Know-How of any Third Party, such Party shall promptly notify the other Parties in writing, and, with respect to activities undertaken pursuant to this Agreement, the Parties shall cooperate and shall mutually agree, through the JSC, upon an appropriate course of action and shall act in accordance with such JSC-approved course of action; provided, however, that, to the extent that any action would involve the enforcement of a Party's Patent Rights or the defense of an Invalidity Claim with respect to a Party's Patent Rights, the general concepts of Section 8.4 shall apply to the enforcement of such Party's Patent Rights or the defense of such Invalidity Claim (i.e., the Owning Party shall have the initial right, and the Non-Owning Party shall have a step-in right in the case of claims in the Field in the U.S. Territory, to enforce or defend). Each Party shall provide to each other Party copies of any notices it receives from Third Parties regarding any patent nullity actions, any declaratory judgment actions, or any alleged infringement or misappropriation of Momenta IP, Sandoz IP or the Patent Rights or Know-How of any Third Party. Such notices shall be provided promptly, but in no event after more than fifteen (15) days following receipt thereof.

8.6. Patent Invalidity Claim. Subject to any contractual obligations to, or restrictions imposed by, a Party's Third Party licensors, if a Third Party at any time asserts a claim that any Momenta IP or Sandoz IP (in each case, other than any Product-Specific Patent Rights relevant to the exercise by Sandoz of the licenses granted in Section 2.1) is invalid or otherwise unenforceable (an "Invalidity Claim"), whether as a defense in an infringement action brought by a Party pursuant to Section 8.4 or in an action brought against a Party under Section 8.5, the general concepts of Section 8.4 shall apply to such Invalidity Claim (i.e., the Owning Party shall have the initial right, and the Non-Owning Party shall have a step-in right in the case of claims in the Field in the U.S. Territory, to defend such Invalidity Claim). No Party shall settle or compromise any Invalidity Claim without obtaining the prior written consent of Momenta or BCWI (or Sandoz, if so designated in writing by the Sandoz Parties), such consent not to be unreasonably withheld, it being understood that the consent of a Third Party licensor of Momenta or BCWI (or Sandoz, if so designated in writing by the Sandoz Parties), respectively, may also be required in order to settle or compromise such Invalidity Claim.

8.7. Joint Collaboration IP and Product-Specific Patent Rights. Subject to any contractual obligations to, or restrictions imposed by, the Parties' Third Party licensors, the JSC shall make all decisions regarding enforcement of the Joint Collaboration IP and of those Product-Specific Patent Rights relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1, in the Field, and responses to any assertions by a Third Party that the Joint Collaboration IP or those Product-Specific Patent Rights relevant to the exercise by the Sandoz Parties of the licenses granted in Section 2.1 are invalid or otherwise unenforceable; provided, however, that, in the event of a dispute within the JSC with respect to such decisions, mutually acceptable outside patent counsel not regularly employed by any Party or their Affiliates shall be retained to resolve such dispute. Each Party shall provide to the other Parties copies of any notices it receives from Third Parties regarding any patent nullity actions, any declaratory judgment actions, any alleged infringement or any alleged misappropriation of the Joint Collaboration IP or those Product-Specific Patent Rights relevant to the exercise by the

Sandoz Parties of the licenses granted in Section 2.1. Such notices shall be provided promptly, but in no event after more than fifteen (15) days following receipt thereof.

8.8. Obligations to Licensors. Notwithstanding anything to the contrary in this Article 8, the terms of this Article 8 are subject to and limited by the provisions of any applicable agreement with Third Party licensors, including, as applicable, the MIT Agreement. Neither Momenta nor the Sandoz Parties shall amend any agreement existing as of the Effective Date (including, without limitation, the MIT Agreement) in a manner that would be inconsistent with this Agreement, nor enter into any agreement after the Effective Date that would be inconsistent with this Agreement.

8.9. Patent Marking. Sandoz shall, and shall cause its Affiliates and distributors, to (a) mark the Product that is manufactured, offered for sale, sold or imported under this Agreement with the number of each issued patent under the Momenta IP, Sandoz IP or Joint Collaboration IP that applies to the Product and (b) comply with the patent marking statutes in each country in which the Product is manufactured by or on behalf of Sandoz or its Affiliates.

9. WARRANTIES

9.1. Representations and Warranties of the Parties. Each of Momenta, on the one hand, and each Sandoz Party, on the other hand, (the "Representing Party") represents and warrants, or covenants, to the Sandoz Parties and Momenta, respectively, that:

9.1.1 The Representing Party is a corporation duly organized, validly existing and in good standing under the laws of its state of incorporation or foreign jurisdiction;

9.1.2 The Representing Party has the requisite corporate power and authority to execute and deliver this Agreement and to perform all of its obligations hereunder. The execution and delivery of this Agreement and the performance by the Representing Party of its obligations hereunder have been authorized by all requisite corporate action on its part. This Agreement has been validly executed and delivered by the Representing Party, and, assuming that such document has been duly authorized, executed and delivered by the other Party, constitutes a valid and binding obligation of the Representing Party, enforceable against such Party in accordance with its terms;

9.1.3 Except as otherwise set forth in this Agreement, no material filing with, and no material permit, authorization, consent or approval of any governmental authority is necessary for the consummation by the Representing Party of the transactions contemplated by this Agreement, except for those filings, permits, authorizations, consents or approvals, the failure of which to be made or obtained would not materially impair such Party's ability to consummate the transactions contemplated hereby or materially delay the consummation of the transactions contemplated hereby;

9.1.4 The execution and delivery of this Agreement by the Representing Party and the performance by such Party of its obligations hereunder, will not (a) violate the certificate of incorporation, by-laws or other organizational document of such Party; (b) conflict in any material respect with or result in a material violation or breach of, or constitute a material default under, any material contract, agreement or instrument to which such Party is bound, or result in the creation of imposition of any material lien upon the Product; or (c) violate or conflict in any material respect with any material law, rule, regulation, judgment, order or decree of any court or governmental authority applicable to such Party or the Product;

9.1.5 The Representing Party has the full power and right to grant to the relevant Party the license rights set forth in Article 2 and Sections 3.4.6, 11.6.1 and 11.6.2, free of any liens or encumbrances (other than the rights of any Third Party licensors therein);

9.1.6 The Representing Party has not, as of the Effective Date, received any notice from any Third Party that the practice of the Momenta IP, if the Representing Party is Momenta, or the Sandoz IP, if the Representing Party is Sandoz or BCWI, infringes any patent or other proprietary rights of any Third Party, and the Representing Party has, as of the Effective Date, no knowledge that any Third Party patent or proprietary rights are infringed as of the Effective Date by the practice by Momenta of the Momenta IP, if the Representing Party is Momenta, or by the practice by the Sandoz Parties of the Sandoz IP, if the Representing Party is Sandoz or BCWI;

9.1.7 As of the Effective Date, there are no interferences or oppositions pending before any court or administrative office or agency relating to the Momenta IP, if the Representing Party is Momenta, or the Sandoz IP, if the Representing Party is Sandoz or BCWI;

9.1.8 To the Representing Party's best knowledge, as of the Effective Date, all Momenta IP, if the Representing Party is Momenta, or Sandoz IP, if the Representing Party is Sandoz or BCWI, is valid and enforceable and has not been challenged in any judicial or administrative proceeding; and

9.1.9 There is no action or proceeding pending or, insofar as the Representing Party knows as of the Effective Date, threatened against the Representing Party before any court, administrative agency or other tribunal that might have a material adverse effect on the Representing Party's performance of this Agreement.

9.2. Momenta Representations. Momenta represents and warrants to Sandoz that Momenta has delivered to Sandoz, on or before the Effective Date, a copy of each invention assignment agreement between Momenta and each employee of Momenta employed as of or prior to the Effective Date, in which such employee has assigned to Momenta all of such employee's rights in any invention which is encompassed by the Momenta IP and which is or

was conceived, reduced to practice or developed by such employee during the term of his or her employment with Momenta.

9.3. Sandoz Parties Representations. Each Sandoz Party represents and warrants to Momenta that Sandoz and BCWI are Affiliates of each other.

9.4. Covenant. In performing its obligations hereunder, Momenta shall not, during the Term, use any research tool, patent or know how for the [**] where the use of such tool, in and of itself, would constitute the willful infringement or misappropriation of the Patent Rights or trade secret rights of any Third Party, it being understood that if a Party becomes aware of such an infringement, or likelihood of or allegation of such an infringement or misappropriation, of the Patent Rights or trade secret rights of a Third Party, the provisions of Section 8.5 shall apply to such circumstance.

9.5. No Reliance by Third Parties. The representations, warranties and covenants of a Party set forth in this Agreement are intended for the sole and exclusive benefit of the other Party hereto and the Indemnified Parties, and may not be relied upon by any Third Party other than the Indemnified Parties, and may only be relied on by the Indemnified Parties for purposes of their indemnity hereunder.

9.6. No Other Warranties. Nothing in this Agreement shall be construed as a representation made or warranty given by any Party that (a) any patents will issue based on pending patent applications, (b) any pending patent applications or patents issued thereon will be valid, or (c) no Third Party will bring a claim against Sandoz, BCWI, Momenta or any of their Affiliates or licensees claiming infringement or misappropriation of such Third Party's Patent Rights, Know-How or confidential information. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

10. CONFIDENTIALITY

10.1. Prior Confidentiality Agreement. Momenta and Sandoz are parties to a certain Confidentiality Agreement dated as of June 17, 2003 (the "Prior Confidentiality Agreement"). The provisions of this Article 10 shall apply to all Confidential Information, and to all Proprietary Information (as that term is defined in the Prior Confidentiality Agreement) disclosed pursuant to the Prior Confidentiality Agreement (which shall be deemed to be Confidential Information, subject to the exceptions in Section 1.18, for purposes of this Agreement). The nature or terms of this Agreement shall be deemed to be Confidential Information of each Party, subject to the exceptions in Section 1.18, for purposes of this Agreement.

10.2. Confidential Information. Each of Sandoz, BCWI and Momenta (the "Receiving Party") shall keep strictly confidential any Confidential Information disclosed by any other Party (the "Disclosing Party"), using at least the same degree of care that it uses to protect its own confidential or proprietary information but in no event less than reasonable care.

10.3. Nondisclosure of Confidential Information. The Receiving Party shall use Confidential Information solely for the purposes of this Agreement and the transactions contemplated hereby and shall not disclose or disseminate any Confidential Information to any Person at any time, except for disclosure to those of its Affiliates, directors, officers, employees, consultants, accountants, attorneys, advisers and agents that have a need to know such information to permit the Receiving Party to exercise its rights or fulfill its obligations pursuant to this Agreement, provided that such Persons are bound to maintain the confidentiality of such Confidential Information to the same extent as if they were parties hereto.

10.4. Exceptions. The foregoing confidentiality and nondisclosure obligations are subject to the following exceptions:

10.4.1 The Receiving Party may disclose the Disclosing Party's Confidential Information that is required to be publicly disclosed by law or by regulation; provided, however, that

a. the Receiving Party shall (i) use its best efforts to ensure that it discloses the minimum amount of the Disclosing Party's Confidential Information necessary to comply with law, (ii) where possible, seeks confidential treatment for any such information which is disclosed to a governmental agency or group, and (iii) provides the Disclosing Party with prompt advance notice of such disclosure (which notice shall be given at least two (2) Business Days in advance of such disclosure if possible) and reasonable opportunity to review any such disclosure so that the Disclosing Party has the opportunity if it so desires to seek a protective order or other appropriate remedy;

b. Momenta shall give Sandoz, on behalf of the Sandoz Parties, a reasonable opportunity to review all filings by Momenta with the United States Securities and Exchange Commission describing the terms of this Agreement prior to submission of such filings, and shall give due consideration to any reasonable comments by Sandoz, on behalf of the Sandoz Parties, relating to such filing, including without limitation the provisions of this Agreement for which confidential treatment should be sought; and

c. the Sandoz Parties or their Affiliates may disclose the terms of this Agreement in any filings with the United States Securities and Exchange Commission (provided that the Sandoz Parties or such Affiliates, as applicable, use Commercially Reasonable Efforts to seek confidential treatment for any financial terms).

10.4.2 Notwithstanding anything to the contrary in this Agreement, each Party, and its employees, representatives or other agents, may disclose to any and all Persons, including, without limitation, the U.S. Internal Revenue Service, the federal tax treatment and tax structure of the transaction and all materials of any kind (including opinions or other tax analyses) that are provided to such Party relating to such tax treatment and tax structure.

10.4.3 Pursuant to an agreement to maintain confidentiality, any Party may discuss the terms of this Agreement with, or provide a copy of this Agreement to, its accountants, its attorneys and its current, future or potential investors or shareholders.

10.4.4 Any Party may discuss the general terms of this Agreement with, but not provide a copy of this Agreement or a redacted copy of this Agreement to, a current, future or potential investor or shareholder who does not execute an agreement to maintain confidentiality, provided that (i) after a preliminary conversation, such Party has used Commercially Reasonable Efforts to have such investor or shareholder execute an agreement to maintain confidentiality and (ii) any disclosure pursuant to this Section 10.4.4 may not include the names of the other Parties, the specific financial terms of this Agreement (including without limitation the specific percentages of Profit Interest and royalties and the details of the payment of the Development Costs, Legal Expenses and FTE's), the specific terms of the rights granted to the Sandoz Parties under Article III, or the specifics of the indemnification provided hereunder (in each case, unless and until such information is otherwise publicly disclosed).

10.4.5 Pursuant to an agreement to maintain confidentiality, Momenta may provide a copy of this Agreement or relevant portions thereof, to MIT and any other Third Party licensor, if required pursuant to the relevant license agreement with respect to Momenta IP.

10.4.6 Any other disclosure of the nature or terms of this Agreement (including, without limitation, any public announcements, press releases or similar publicity with respect to this Agreement) by Momenta, on the one hand, or either Sandoz Party, on the other hand, must be approved in advance in writing by Sandoz or Momenta, respectively, as to form and content of such disclosure; provided, however, that the contents of any public announcement, press release or similar publicity which has been reviewed and approved by the reviewing Party can be re-released by either Party in any form without a requirement for re-approval. The Parties agree that Momenta and the Sandoz Parties (or an Affiliate thereof) shall issue a joint press release in a mutually agreeable form on an agreed upon date within fourteen (14) days after the mutual execution and delivery of this Agreement to all Parties.

10.5. Identification. In any disclosure by Sandoz or BCWI permitted hereunder which refers to Momenta IP or the Joint Collaboration IP, Sandoz or BCWI, as the case may be, shall identify Momenta as the inventor, co-inventor, originator, owner, co-owner and/or licensee, as appropriate, of such Momenta IP or Joint Collaboration IP. In any disclosure by Momenta permitted hereunder which refers to Sandoz IP or Joint Collaboration IP, Momenta shall identify Sandoz or BCWI as the inventor, co-inventor, originator, owner, co-owner and/or licensee, as appropriate, of such Sandoz IP or Joint Collaboration IP.

10.6. Equitable Relief. The Receiving Party agrees that any breach of this Article 10 may cause the Disclosing Party substantial and irreparable injury and, therefore, in the event of any such breach, in addition to other remedies that may be available, the Disclosing Party shall have the right to specific performance and other injunctive and equitable relief.

10.7. Survival. The confidentiality and nondisclosure obligations of this Article 10 shall survive the expiration or termination of this Agreement and remain in effect for a period of ten (10) years following the expiration or termination of this Agreement.

11. TERM & TERMINATION

11.1. Term. The term of this Agreement (the "Term") shall begin on the Effective Date and continue until the last sale of the Product by Sandoz, its Affiliates or distributors anywhere in the U.S. Territory, unless earlier terminated by either Party pursuant to the provisions of this Agreement.

11.2. Termination For Cause.

11.2.1 Momenta, on the one hand, and Sandoz (on behalf of the Sandoz Parties), on the other hand, may terminate this Agreement for any breach of a material provision by a Sandoz Party or Momenta, respectively, thirty (30) days after written notice containing details of the breach if the breach remains uncured at the end of the notice period.

11.2.2 Notwithstanding Section 11.2.1, in the event that the Sandoz Parties are unable to perform any of their respective obligations under this Agreement as a result of any interruption of the Supply Chain or manufacturing capability for the Product, including as a result of any action taken or threatened by the FDA or other Regulatory Authority (each such event a "Supply Interruption"), and such inability to perform hereunder would otherwise constitute a breach of a material provision of this Agreement, and such breach is not cured within thirty (30) days following receipt by Sandoz (on behalf of the Sandoz Parties) of written notice from Momenta of such breach, such Supply Interruption shall not be considered a breach of this Agreement provided that Sandoz (on behalf of the Sandoz Parties) provides the JSC with written notice and evidence, in form and substance reasonably satisfactory to the JSC, that the alleged breach is as a result of a Supply Interruption within fifteen (15) days following receipt by Sandoz (on behalf of the Sandoz Parties) from Momenta of notice of such alleged breach (a "Supply Interruption Notice"). Such Supply Interruption Notice shall extend the thirty (30) day cure period set forth in Section 11.2.1 in accordance with the following procedure: (a) Sandoz (on behalf of the Sandoz Parties) shall furnish to the JSC a written plan (the "Supply Continuation Plan") within thirty (30) days following the JSC's receipt of the Supply Interruption Notice setting forth the actions that the Sandoz Parties shall take to cure the Supply Interruption as soon as commercially possible following the occurrence of the Supply Interruption; (b) the Supply Continuation Plan shall be subject to the review and approval of the JSC, which shall not be unreasonably withheld, conditioned or delayed; (c)

following the JSC's review and approval of the Supply Continuation Plan, such plan may be amended or modified with the prior consent and approval of the JSC, which shall approve any reasonable request by the Sandoz Parties for such an amendment or modification; and (d) the Sandoz Parties shall not be considered in breach of this Agreement under Section 11.2.1 as a result of the Supply Interruption if the Supply Continuation Plan is approved by the JSC and the Sandoz Parties use Commercially Reasonable Efforts to execute the Supply Continuation Plan.

11.2.3 To the extent permitted under applicable law, Momenta, on the one hand, and Sandoz (on behalf of the Sandoz Parties), on the other hand, may terminate this Agreement effective immediately with written notice if a Sandoz Party or Momenta, respectively, shall file for bankruptcy, shall be adjudicated bankrupt, shall file a petition under insolvency laws, shall be dissolved or shall have a receiver appointed for substantially all of its property.

11.2.4 With respect to a default or breach of this Agreement, failure of a Party to provide notice to the defaulting or breaching Party provided in this Article 11 shall not constitute a waiver of the right to give such notice with respect to any subsequent default or breach.

11.3. Termination Due to Lack of Commercial Viability. If (a) there is a withdrawal from the market of all Lovenox®-Equivalent Products due to material safety concerns, which withdrawal could significantly impact the commercial viability of the Product, (b) a new product [**] enters the market and the number of units of [**] sold during the immediately following [**] period is less than [**] percent ([**]%) of the number of units sold in the twelve-month period immediately prior to such entry, (c) at least [**] Products (other than [**]) have been on the market in the U.S. Territory for at least [**] each prior to the U.S. Launch, (d) at least [**] Third-Party Competitors have received tentative approval of [**] Products prior to Sandoz's receipt of tentative approval of the [**] for the Product or (e) the Product fails to generate Profits equal to or greater than [**] percent ([**]%) of corresponding Net Sales for any Post-Launch Year during the Post-[**] Period, the [**] Period or the Aventis [**] Period (each, a "Commercial Viability Trigger"), then, for a period of thirty (30) days after the occurrence of such Commercial Viability Trigger, Sandoz (on behalf of the Sandoz Parties) shall have the right to terminate this Agreement upon thirty (30) days' prior written notice to Momenta. The termination rights specified in this Section 11.3 shall be termed a "Commercial Viability Termination".

11.4. Sandoz Milestone Termination. If, for any reason other than as a result of a breach by Sandoz or BCWI under this Agreement, (a) the drug product form of the Product is not ready for initiation of Stability Studies on or before December 31, 2004, or (b) during the course of the Parties' attempt to achieve District Court Legal Clearance, a decision by a District Court , a United States Court of Appeals, or the United States Supreme Court is issued, or an applicable law or regulation is enacted or amended, which materially and substantially diminishes achievement of Final Legal Clearance based on the legal theories and strategies then being pursued by the Parties to achieve District Court Legal Clearance (including, without limitation, a

District Court Decision that the marketing of the Product by Sandoz or its Affiliates would infringe Aventis' Patent Rights) (a "Legal Strategy Diminishment") (each of subsections 11.4(a) and 11.4(b) a "Sandoz Milestone Trigger"), then for a period of sixty (60) days after the later of the occurrence of such Sandoz Milestone Trigger or Sandoz's actual knowledge of such Sandoz Milestone Trigger, Sandoz (on behalf of the Sandoz Parties) shall have the right to terminate this Agreement upon thirty (30) days prior written notice to Momenta (provided, however, that, (i) if there is a dispute between the Parties as to whether a Legal Strategy Diminishment has occurred, outside patent counsel not regularly employed by any Party or their Affiliates who is mutually acceptable to the Parties shall be retained to resolve such dispute, and (ii) if there is a dispute between the Sandoz Parties, on the one hand, and Momenta, on the other hand, as to whether a Sandoz Milestone Trigger has occurred, the Agreement shall not be terminated pursuant to this Section 11.4 unless and until such dispute is resolved, in accordance with the terms of this Agreement, in Sandoz's favor). The termination rights specified in this Section 11.4 shall be termed a "Sandoz Milestone Termination".

11.5. Excessive Cost Termination. Sandoz (on behalf of the Sandoz Parties) shall have the right to terminate this Agreement in the event of excessive Capped Costs, as follows:

11.5.1 In the event that, prior to the U.S. Launch, the Capped Costs exceed the Cost Cap (the "Initial Excessive Cost Trigger"), Sandoz shall have the option, in its sole discretion, to terminate this Agreement (the "Initial Excessive Cost Termination") effective immediately upon written notice thereof to Momenta, which option may be exercised by Sandoz within sixty (60) days after the Parties have, pursuant to Section 4.1, exchanged the written reports and invoices which reflect that the Initial Excessive Cost Trigger was achieved in the prior Quarter (the "Initial Excessive Cost Termination Option Period"). Notwithstanding Section 4.1, in the event of an Initial Excessive Cost Termination, the Sandoz Parties shall not be responsible for any Capped Costs in excess of the Cost Cap, except as provided in Section 11.6.1. If Sandoz does not exercise its right to an Initial Excessive Cost Termination, the Sandoz Parties shall continue to be responsible for Capped Costs in excess of the Cost Cap, subject to the provisions of Section 11.5.2 and Schedule 4.3.

11.5.2 If, prior to the U.S. Launch, (a) the Capped Costs exceed the Cost Cap by more than the then-current Additional Costs Amount and (b) more than twelve (12) months have elapsed since the expiration of the immediately preceding Excessive Cost Termination Option Period (each, an "Additional Excessive Cost Trigger"), Sandoz shall have the option, in its sole discretion, to terminate this Agreement (each, an "Additional Excessive Cost Termination") effective immediately upon written notice thereof to Momenta, which option may be exercised by Sandoz within sixty (60) days after the later of (i) the exchange by the Parties, pursuant to Section 4.1, of the written reports and invoices which reflect that such Additional Excessive Cost Trigger was achieved in the prior Quarter (each, an "Additional Excessive Cost Termination Option Period") or (ii) the end of such twelve-month period. Notwithstanding Section 4.1, in the event of an Additional Excessive Cost Termination, the Sandoz Parties shall not be

responsible for any Capped Costs in excess of the amount that triggered the applicable Additional Excessive Cost Trigger, except as provided in Section 11.6.1. If Sandoz does not exercise its right to an Additional Excessive Cost Termination, (A) the Sandoz Parties shall continue to be responsible for Capped Costs in excess of the sum of the Cost Cap and the then-current Additional Costs Amount, subject to the provisions of this Section 11.5.2 and Schedule 4.3, and (B) the Additional Costs Amount shall be increased by Three Million Dollars (U.S.$3,000,000).

11.6. Effects of Termination.

11.6.1 In the event of termination of this Agreement by Sandoz (on behalf of the Sandoz Parties) pursuant to Sections 11.3, 11.4 or 11.5, or by Momenta pursuant to Section 11.2, (a) all licenses granted by Momenta to the Sandoz Parties or their Affiliates shall terminate; (b) all licenses granted by the Sandoz Parties to Momenta under Article 2 shall remain in effect on an irrevocable, perpetual, sublicenseable (provided that such sublicensees comply with the relevant provisions of this Agreement) and exclusive basis and shall be converted to licenses to (i) Develop, make, have made, use, sell, offer to sell, lease, import and export the Product in the Field anywhere in the world (subject to the terms of the Non-U.S. Territory Agreement, if such has been executed prior to the date of termination of this Agreement) and (ii) make, have made and use the Product in the Non-U.S. Territory (subject to the terms of the Non-U.S. Territory Agreement, if such has been executed prior to the date of termination of this Agreement) but only for the purposes of sale of the Product in or into the U.S. Territory and any country which is not subject to the terms of the Non-U.S. Territory Agreement; (c) the license granted by the Sandoz Parties to Momenta pursuant to Section 3.4.6 shall remain in effect on an irrevocable and perpetual basis; (d) each of Sandoz and BCWI shall cease to use and shall assign to Momenta all of its right, title and interest in and to all clinical, technical and other relevant reports, records, data, information and materials relating to the Product and all regulatory filings and Marketing Approvals in the U.S. Territory relating to the Product (and the Sandoz Parties shall deliver to Momenta, at Momenta's expense (or at Sandoz's expense in the case of termination by Momenta under Section 11.2), one (1) copy of each physical embodiment of the aforementioned items within thirty (30) days after termination); (e) Sandoz and BCWI shall cease to use in the Field any technology arising out of the Collaborative Program, including, without limitation, any manufacturing processes; (f) Sandoz and BCWI shall promptly return to Momenta all materials and records in their possession or control containing Confidential Information of Momenta; (g) Sandoz and BCWI shall transfer and assign to Momenta all trademarks and tradenames of the Product that have received Marketing Approval in the U.S. Territory, except for any such trademarks or tradenames or a part thereof that use the name "Novartis" or "Sandoz" or a derivative thereof or any other trademark or tradename or part or derivative thereof that is the name or derivative of a name of any other Sandoz Affiliate; (h) if so requested by Momenta, the Sandoz Parties shall, at Momenta's

expense (or at Sandoz's expense in the case of termination by Momenta under Section 11.2), take reasonable steps to assist Momenta in establishing a contract manufacturing relationship with their suppliers (if any) of the Product, it being understood that Sandoz and BCWI in no way guarantees the ability to transfer any such relationship to Momenta; (i) at Momenta's request, Sandoz and BCWI shall sell to Momenta at Manufacturing Cost all units of the Product, whether in finished product or work-in-process form, in their inventory for sale in or into the U.S. Territory; (j) subject to any contractual obligations to, or restrictions imposed by, the Sandoz Parties' Third Party licensors, the Sandoz Parties shall continue to use Commercially Reasonable Efforts to timely prepare, file, prosecute and maintain, at their expense, Sandoz Patent Rights and Sandoz Collaboration Patent Rights in the Field in the U.S. Territory; provided, however, that if the Sandoz Parties decline to file, prosecute or maintain any such Patent Right or if the Sandoz Parties elect to allow any such Patent Right to lapse or elects to abandon any such Patent Right before all appeals within the respective patent office have been exhausted, then, subject to any contractual obligations to, or restrictions imposed by, the Sandoz Parties' Third Party licensors, (1) Momenta shall have the right, at its own expense and upon written notice to the relevant Sandoz Party(ies), to assume control of the filing, prosecution and maintenance of such Patent Right in the relevant Sandoz Party's name or the name of its Third Party licensor, as applicable, in which event, the relevant Sandoz Party shall provide assistance to and cooperate with Momenta in prosecuting the subject Patent Right, should Momenta elect to prosecute and maintain the subject Patent Right, and (2) the relevant Sandoz Party shall provide Momenta with reasonable notice of its decision to decline to file, prosecute or maintain any such Patent Right or its election to allow any such Patent Right to lapse or its election to abandon any such Patent Right so as to permit Momenta (A) to review the patent or application, (B) to decide whether to prosecute or maintain the same, and (C) to take appropriate action to prosecute or maintain the patent application or patent; (k) the provisions of Sections 8.4 and 8.8 shall continue to apply with respect to Sandoz Patent Rights (and, notwithstanding anything therein, any Product-Specific Patent Rights therein) in the Field in the U.S. Territory; and (l) the Sandoz Parties shall be responsible for all amounts incurred and owing to Momenta pursuant to Article 4 hereof (as modified by Schedule 4.3, as applicable) prior to the date of termination but not previously paid, which payments shall be made in the time and manner provided under Article 4. The post-termination license rights granted to Momenta in (b) and (c) of this subsection shall apply only as to any Sandoz IP that has actually been used in the Collaborative Program prior to the date of termination of this Agreement, and shall expressly exclude any other Sandoz IP.

11.6.2 In the event of termination of this Agreement by Sandoz (on behalf of the Sandoz Parties) pursuant to Section 11.2, (a) all licenses granted by the Sandoz Parties to Momenta shall terminate; (b) all licenses granted by Momenta to the Sandoz Parties under this Agreement shall remain in effect on an irrevocable, perpetual, sublicenseable (provided that such sublicensees comply with the

relevant provisions of this Agreement) and exclusive basis; (c) Momenta shall cease to use and shall assign to Sandoz all of its right, title and interest in and to all clinical, technical and other relevant reports, records, data, information and materials relating to the Product and all regulatory filings and Marketing Approvals in the U.S. Territory relating to the Product (and Momenta shall deliver to Sandoz, at Momenta's expense, one (1) copy of each physical embodiment of the aforementioned items within thirty (30) days after termination); (d) Momenta shall promptly return to Sandoz or BCWI, as the case may be, all materials and records in Momenta's possession or control containing Confidential Information of Sandoz or BCWI, respectively; (e) subject to any contractual obligations to, or restrictions imposed by, Momenta's Third Party licensors, Momenta shall continue to use Commercially Reasonable Efforts to timely prepare, file, prosecute and maintain, at its expense, Momenta Patent Rights and Momenta Collaboration Patent Rights in the Field in the U.S. Territory; provided, however, that if Momenta declines to file, prosecute or maintain any such Patent Right or if Momenta elects to allow any such Patent Right to lapse or elects to abandon any such Patent Right before all appeals within the respective patent office have been exhausted, then, subject to any contractual obligations to, or restrictions imposed by, Momenta's Third Party licensors, (1) BCWI (or Sandoz, if so designated in writing by the Sandoz Parties) shall have the right, at its own expense and upon written notice to Momenta, to assume control of the filing, prosecution and maintenance of such Patent Right in Momenta's name or the name of its Third Party licensor, as applicable, in which event, Momenta shall provide assistance to and cooperate with BCWI (or Sandoz, if so designated in writing by the Sandoz Parties) in prosecuting the subject Patent Right, should BCWI (or Sandoz, if so designated in writing by the Sandoz Parties) elect to prosecute and maintain the subject Patent Right, and (2) Momenta shall provide BCWI (or Sandoz, if so designated in writing by the Sandoz Parties) with reasonable notice of its decision to decline to file, prosecute or maintain any such Patent Right or its election to allow any such Patent Right to lapse or its election to abandon any such Patent Right so as to permit BCWI (or Sandoz, if so designated in writing by the Sandoz Parties) (A) to review the patent or application, (B) to decide whether to prosecute or maintain the same, and (C) to take appropriate action to prosecute or maintain the patent application or patent; (f) the financial obligations set forth in Article 4 (other than Sections 4.1 and 4.2), including the provisions of Schedule 4.3, each as applicable, the patent marking obligations set forth in Section 8.9, and the insurance obligations of Section 12.4 shall remain in effect; (g) in the event the Sandoz Parties' rights under Section 3.4 have not yet lapsed at the time of termination, the rights of the Sandoz Parties under Section 3.4 shall survive in accordance with the terms thereof; (h) subject to the provisions of Article 3, for as long as Sandoz is marketing the Product and abiding by its financial obligations to Momenta pursuant to subsection (f) of this Section 11.6.2, Momenta shall not provide any Patent Rights, Know-How or any other assistance to any third party to Characterize, develop, produce, manufacture or Commercialize Lovenox®-Equivalent Products in the Field in the U.S. Territory, or, in the event that the Sandoz Parties' rights under Section 3.4 have not yet lapsed at the time of such

termination, worldwide; and (i) the provisions of Sections 8.4 and 8.8 shall continue to apply with respect to Momenta Patent Rights (and, notwithstanding anything therein, any Product-Specific Patent Rights therein) in the Field in the U.S. Territory. The post-termination license rights granted to the Sandoz Parties in (b) and (c) of this subsection shall apply only as to any Momenta IP that has actually been used in the Collaborative Program prior to the date of termination of this Agreement, and shall expressly exclude any other Momenta IP.

11.6.3 In the event that, subsequent to any Initial Excessive Cost Termination or Additional Excessive Cost Termination, Momenta, its Affiliates, licensees or distributors is selling the Product in the U.S. Territory, then, in addition to the provisions of Section 11.6.1, for each Quarter during which Momenta, its Affiliates or licensees is selling the Product in the U.S. Territory, Momenta shall pay the Sandoz Parties (in the proportion designated by Sandoz) a royalty (the "Sandoz Parties Royalty") as a percentage of Net Sales by Momenta, its Affiliates, licensees or distributors of the Product in the U.S. Territory, to be computed according to the following table, by multiplying Net Sales by Momenta, its Affiliates or licensees in the U.S. Territory for such Quarter times the applicable percentage listed in the table:

	Royalty Rate	
Net Sales in the U.S. Territory During such Quarter	[**]	[**]
For all such Net Sales	[**]%	[**]%

If, during a particular Quarter, the number of Third-Party Competitors changes, the Sandoz Parties Royalty shall be paid based on actual Net Sales made during such Quarter under the respective royalty rates.

11.7. Bankruptcy. All rights and licenses granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

11.8. Survival. Upon expiration or termination of this Agreement for any reason, (a) nothing in this Agreement shall be construed to release either Party from any obligations that were incurred prior to the effective date of expiration or termination; (b) the following provisions shall expressly survive any such expiration or termination: Articles 1, 10 and 14, Sections 2.5, Article 3 (to the extent that the Agreement has terminated as a result of a breach by Momenta

under Section 11.2), Sections 4.11, 4.12, 8.1, 8.2.3, 9.6, 11.6 (as applicable), 11.7, 11.8, 11.9, 13.2, 13.3, and Schedule 4.3 (to the extent applicable); and (c) (i) the obligations to indemnify under Sections 12.1 and 12.2 (subject to Section 12.3) shall survive the expiration or termination of this Agreement with respect to any Liabilities, whether asserted during or after the Term, that result from activities that occurred before or during the Term, (ii) the obligations of Momenta to indemnify the Sandoz Indemnified Parties under Section 12.2 (subject to Section 12.3) shall survive the expiration or termination of this Agreement with respect to any Liabilities that result from activities that occur after the Term pursuant to Section 11.6.1, (iii) the obligations of the Sandoz Parties to indemnify the Momenta Indemnified Parties under Section 12.1 (subject to Section 12.3) shall survive the expiration or termination of this Agreement with respect to any Liabilities that result from activities that occur after the Term pursuant to Section 11.6.2, and (iv) otherwise there shall be no continuing obligation of the Indemnifying Party to indemnify, defend or hold harmless the Indemnified Party after the date of expiration or termination of this Agreement.

11.9. Non-Exclusive Remedy. Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including, without limitation, the Parties' ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

12. INDEMNIFICATION

12.1. Sandoz Indemnification of Momenta. The Sandoz Parties shall indemnify, defend and hold harmless the Momenta Indemnified Parties from and against all losses, costs, damages, judgments, settlements, interest, fees or expenses (including all reasonable attorneys' fees, experts' or consultants' fees, expenses and costs) ("Liabilities") awarded to a Third Party against any Momenta Indemnified Party, or that may be incurred or paid by any Momenta Indemnified Party in the defense or compromise of legal or equitable claims asserted by a Third Party, arising out of or resulting from (a) any breach of any obligation by Sandoz or BCWI hereunder, (b) any misrepresentation by Sandoz or BCWI hereunder (including but not limited to any such breach by Sandoz or BCWI of Article 9 — Warranties), (c) any Patent Litigation, (d) any property damage or personal injury (including, without limitation, death) resulting from the development, use, manufacture, sale, offering for sale or importation of the Product by Sandoz, its Affiliates or their Third Party contractors or distributors, or (e) any claims or demands related to the Product that are commenced by [**] any Third Party against any Momenta Indemnified Party based on the activities of Momenta or the Sandoz Parties (including those undertaken by Affiliates or Third Parties on behalf of Momenta or the Sandoz Parties) [**] pursuant to this Agreement; provided, however, that the Sandoz Parties shall have no obligation to indemnify the Momenta Indemnified Parties against Liabilities under (a) through (e) to the extent that such Liabilities arise from any Third Party legal or equitable claim that is subject to Momenta's obligation to indemnify, defend, and hold the Sandoz Indemnified Parties harmless under Section 12.2.

12.2. Momenta Indemnification of Sandoz. Momenta shall indemnify, defend and hold harmless the Sandoz Indemnified Parties from and against all Liabilities awarded to a Third Party against the Sandoz Indemnified Parties or that may be incurred or paid by any of the Sandoz Indemnified Parties in the defense or compromise of legal or equitable claims asserted by

a Third Party, arising out of or resulting from (a) any breach of any obligation by Momenta hereunder, including, without limitation, the covenant in Section 9.4, (b) any misrepresentation by Momenta hereunder (including but not limited to any such breach by Momenta of Article 9 — Warranties) of this Agreement, or (c) any actual misappropriation by any Momenta Indemnified Party of any Third Party trade secret or know-how, provided that, (i) with respect to actual misappropriation, there has been a final adjudication of liability for misappropriation by a court of competent jurisdiction, or, (ii) with respect to misappropriation that has been alleged but not finally adjudicated, there is a settlement with a Third Party which the Parties determine by mutual agreement constitutes an acknowledgement by Momenta of actual misappropriation. (either case under (i) or (ii) being a "Final Misappropriation Determination"). If there is a dispute between the Parties as to whether a settlement constitutes such an acknowledgement, nationally-recognized outside counsel not regularly employed by any Party or their Affiliates who is mutually acceptable to the Parties shall be retained to resolve such dispute. In the event that Sandoz has, pursuant to the provisions of Section 12.1, incurred Liabilities with respect to an actual or alleged misappropriation by any Momenta Indemnified Party of any Third Party trade secret or know-how and a Final Misappropriation Determination occurs, Momenta shall, in addition to indemnifying the Sandoz Indemnified Parties for such Liabilities incurred by them pursuant to subsection (c) of this Section 12.2, reimburse Sandoz for any Liabilities which Sandoz previously paid to or incurred on behalf of any of the Momenta Indemnified Parties that are allocable to the misappropriation claim that gave rise to the Final Misappropriation Determination.

12.3. Procedure. If any Momenta Indemnified Party or any Sandoz Indemnified Party (in each case, an "Indemnified Party") receives any written claim or demand which such Indemnified Party believes is the subject of indemnity hereunder by Sandoz or Momenta as the case may be (in each case, an "Indemnifying Party"), the Indemnified Party shall, as soon as reasonably practicable after forming such belief, give notice thereof to the Indemnifying Party; provided that the failure to give timely notice to the Indemnifying Party as contemplated hereby shall not release the Indemnifying Party from any liability to the Indemnified Party unless the Indemnifying Party demonstrates that the defense of such claim is materially prejudiced by such failure. The Indemnifying Party shall assume and diligently pursue the defense of such claim, at its cost, with counsel reasonably satisfactory to the Indemnified Party. The Indemnifying Party shall have absolute control of the conduct of the litigation; provided, however, that

12.3.1 the Indemnified Party may, nevertheless, participate therein through counsel of its choice and at its cost, and shall be permitted to effectively associate with the Indemnifying Party in the defense, the prosecution and the negotiation of any settlement of the claim or demand;

12.3.2 the Indemnifying Party shall keep the Indemnified Party informed, through the JSC, of the status of the litigation;

12.3.3 the Indemnifying Party shall provide the Indemnified Party with a reasonable opportunity to review and comment on all pleadings, motions and other papers exchanged with the opposing party or filed with any court by the Indemnifying Party with respect to such claim or demand (collectively, the

"Pleadings") and the Indemnifying Party shall consider in good faith any input provided by the Indemnified Party with respect to the Pleadings; and

12.3.4 if the suit includes a defense of Momenta IP or an Invalidity Claim with respect to Momenta IP or the Joint Collaboration IP (in the event Momenta is the Indemnified Party), then the Indemnifying Party's conduct of the litigation with respect to such claim(s) shall be subject to:

a. the approval of Momenta and/or

b. any contractual obligations to, or restrictions imposed by, the relevant Third Party licensor.

The Party not assuming the defense of any such claim or demand shall render all reasonable assistance to the Party assuming such defense as requested by such defending Party, and all reasonable out-of-pocket costs of such assistance shall be for the account of the Indemnifying Party. No such claim or demand shall be settled other than by the Party defending the same, and then only with the consent of the other Party, which shall not be unreasonably withheld; provided that the Indemnified Party shall have no obligation to consent to any settlement of any such claim which imposes on the Indemnified Party any liability or obligation which cannot be assumed and performed in full by the Indemnifying Party (subject, in the case of a Settlement, to the terms of Section 4.3) or which agrees that any element of any of Momenta IP or Joint Collaboration IP (in the event Momenta is the Indemnified Party) is invalid, not infringed or unenforceable.

12.4. Insurance. The Sandoz Parties shall be self-insured. To the extent Momenta is required to obtain the consent or waiver of MIT under the MIT Agreement to permit such self-insurance by the Sandoz Parties, Momenta shall use its best efforts to obtain such waiver or consent. Momenta shall comply with the insurance obligations imposed on Momenta pursuant to the MIT Agreement.

13. DISPUTE RESOLUTION

13.1. First Level Resolution. Unless otherwise expressly provided for herein, any claim or controversy between Momenta, on the one hand, and the Sandoz Parties, on the other hand, arising out of or relating to the execution, interpretation and performance of this Agreement (including the validity, scope and enforceability of this provision) which has not been resolved by the JPT will be identified in writing and presented by the JPT to the JSC. The JSC shall meet within fourteen (14) days after delivery of the notice of dispute pursuant to this Section 13.1 and attempt in good faith to resolve the dispute. If the JSC is unable to decide or resolve an issue unanimously or in the event of any dispute or claim arising out of or relating to this Agreement, or to the breach, termination, or validity of this Agreement a notice of dispute shall be submitted to the relevant Executive Officers of the Parties for resolution by good-faith negotiations pursuant to Section 13.2.

13.2. Negotiation Between Executives. Within fourteen (14) days after delivery of the notice of dispute pursuant to Section 13.1, the Sandoz Executive Officer (unless the Sandoz Parties designate, within one (1) Business Day after delivery of the notice of dispute pursuant to

Section 13.1, that the BCWI Executive Officer shall participate instead) and the Momenta Executive Officer shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the dispute in good faith. All reasonable requests for information made by one Party to another will be honored. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. If such Executive Officers cannot resolve such dispute within fourteen (14) days after such meeting, then each Party reserves its right to any and all remedies available under law or equity with respect to any other dispute. Notwithstanding the foregoing, such Executive Officers shall meet and attempt to resolve any dispute regarding the strategy to achieve Legal Clearance within seven (7) days (or such other mutually agreed period) after delivery of the notice of dispute pursuant to Section 13.1, and, if such Executive Officers cannot resolve such dispute within such time period, then (except as provided in Section 11.4) such dispute shall be considered resolved in Sandoz's favor.

13.3. Legal Remedies. Notwithstanding anything to the contrary in this Article 13, any Party may seek immediate injunctive or other interim relief from any court of competent jurisdiction as necessary to enforce and prevent infringement or misappropriation of the patent rights, copyright rights, trademarks, confidential information, trade secrets, or other intellectual property rights owned or controlled by a Party or its Affiliates or to prevent breach of Article 10.

14. ADDITIONAL PROVISIONS

14.1. Entire Agreement. This Agreement, including the Schedules hereto, contains the entire agreement and understanding between the Parties relating to the subject matter hereof and all prior agreements and understandings between the Parties and relating to the subject matter hereof, including, without limitation, the Prior Confidentiality Agreement, are superseded by this Agreement. Neither Party shall be liable or bound to any other Party in any manner by any representations, warranties or covenants relating to such subject matter except as specifically set forth herein.

14.2. Amendments and Waiver. This Agreement may not be amended except by an instrument in writing signed on behalf of each of the Parties. By an instrument in writing either Party may waive compliance by the other Party with any term or provision of this Agreement that such other Party was or is obligated to comply with or perform. Any failure of a Party to enforce at any time, or for any period of time, any of the provisions of this Agreement shall not be deemed or construed to be a waiver of such provisions or a waiver of any right of such Party thereafter to enforce each and every such provision on any succeeding occasion or breach thereof.

14.3. Assignment. This Agreement shall be assignable only: (a) by a Party to an Affiliate of that Party, without the consent of the other Parties, provided that in such case, the assigning Party remains liable with the assignee for all of its obligations hereunder; (b) by a Party with the written consent of the other Parties; or (c) automatically by a Party without the consent of the other Parties to (i) the purchaser of (A) all or substantially all of the assets, or (B) a majority of the voting equity securities, of the assigning Party's business to which this Agreement relates, or (ii) the surviving Person, in the event of a merger of the assigning Party

and another Person, and any such purchaser or successor shall be bound by the terms hereof. Any attempted assignment that does not comply with the terms of this Section 14.3 shall be void. This Agreement shall be binding upon and inure to the benefit of the Parties, their successors and permitted assigns.

14.4. Nature of Relationship. In making and performing this Agreement, the Parties are acting, and intend to be treated, as independent entities and nothing contained herein shall be deemed or implied to create an agency, distributorship, joint venture or partnership relationship among the Parties hereto. Except as otherwise expressly provided herein, no Party may make any representation, warranty or commitment, whether express or implied, on behalf of or incur any charges or expenses for, or in the name of, any other Party. Except as provided in Article 12 or Section 4.11.8, no Party shall be liable for the act of any other Party unless such act is expressly authorized in writing by the Parties hereto.

14.5. Notices. All notices and other communications required or permitted to be given or made pursuant to this Agreement shall be in writing signed by the sender and shall be deemed duly given (a) on the date delivered, if personally delivered, (b) on the date sent by telecopier with automatic confirmation by the transmitting machine showing the proper number of pages were transmitted without error, (c) on the Business Day after being sent by Federal Express or another recognized overnight mail service which utilizes a written form of receipt for next day or next business day delivery, or (d) two (2) Business Days after mailing, if mailed by United States postage-prepaid certified or registered mail, return receipt requested, in each case addressed to the applicable party at the address set forth below; provided that a Party may change its address for receiving notice by the proper giving of notice hereunder:

If to Sandoz:

Geneva Pharmaceuticals, Inc.
506 Carnegie Center, Suite 400
Princeton, NJ 08540
Attn: Chief Executive Officer
Tele: (609) 627-8500
Fax: (609) 627-8684

With a copy to:

Geneva Pharmaceuticals, Inc.
506 Carnegie Center, Suite 400
Princeton, NJ 08540
Attn: Chief Executive Officer
Tele: (609) 627-8500
Fax: (609) 627-8684

If to Momenta:

Momenta Pharmaceuticals, Inc.
43 Moulton Street
Cambridge, MA 02138
Attn: Chief Executive Officer
Tele: 617-491-9700
Fax: 617-491-9701

With a copy to:

Hale and Dorr LLP
60 State Street
Boston, MA 02109
Attn: Steven D. Singer, Esq.
Tele: (617) 526-6000
Fax: (617) 526-5000

If to BCWI:

Biochemie West Indies N.V.
Pietermaai 6A
Willemstad, Curacao
Netherlands Antilles
Attn: Guido Schwaiger, Head Caribic
Tele: 599-9-461-4084
Fax: 599-9-461-1460

If to Sandoz GmbH:

Sandoz GmbH
Biochemiestrasse 10
Kundl, Austria
Attn: Legal Counsel
Tele: 01143 5338 200 2207
Fax: 01143 5338 8828

With a copy to:
Sandoz GmbH
Biochemiestrasse 10
Kundl, Austria
Attn: Legal Counsel
Tele: 01143 5338 200 2207
Fax: 01143 5338 8828

14.6. Governing Law. This Agreement and any and all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the internal laws of the State of New York applicable to agreements made and to be performed entirely in such state, without giving effect to the conflict of law principles thereof.

14.7. Jury Waiver. EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY CLAIM BASED UPON, DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY. EACH PARTY HERETO ACKNOWLEDGES THAT IT AND THE OTHER PARTY HERETO HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 14.7.

14.8. Counterparts; Facsimile Signature. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may also be executed via facsimile, which shall be deemed an original.

14.9. Severability. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstances, is held invalid, illegal or unenforceable in any respect for any reason, the Parties shall negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; provided, however, that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions contained herein shall not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto shall be enforceable to the fullest extent permitted by law.

14.10. Expenses. Each Party hereto shall bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.

14.11. Further Actions and Documents. Each Party agrees to execute, acknowledge and deliver all such further instruments, and to do all such further acts, as may be reasonably necessary or appropriate to carry out the intent and purposes of this Agreement.

14.12. Use of Trade Names and Trademarks. Each Party recognizes that the name of the other Party represents valuable assets of such other Party and that substantial recognition and goodwill are associated with such assets. Each Party hereby agrees that neither it nor any of its Affiliates shall use such assets of the other Party without prior written authorization from such other Party. Nothing in this Agreement constitutes a license entitling any Party to use any other Party's name, logos or trademarks; provided, however, that any Party may use any other Party's name, logos or trademarks to the extent permitted in Section 10.4.

14.13. Affiliates. To the extent that the rights granted to a Party hereunder may be and are exercised by an Affiliate of such Party, such Affiliate shall be bound by the corresponding obligations of such Party.

14.14. Exports. The Parties acknowledge that the export of technical data, materials or products is subject to the exporting Party receiving any necessary export licenses and that the Parties cannot be responsible for any delays attributable to export controls that are beyond the reasonable control of either Party. The Parties agree not to export or re-export, directly or indirectly, any information, technical data, the direct product of such data, samples or equipment received or generated under this Agreement in violation of any governmental regulations that may be applicable. The Parties agree to obtain similar covenants from their licensees with respect to the subject matter of this Section 14.14.

14.15. Force Majeure. No failure or omission by a Party hereto in the performance of any obligation of this Agreement (excluding payment obligations) shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the reasonable control of such Party, including, but not limited to, the following: acts of God; acts or omissions of any government; any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; fire; storm; flood; earthquake; accident; war; rebellion; terrorism; insurrection; riot; and invasion (a "Force Majeure Event"); and provided that such failure or omission resulting from a Force Majeure Event is cured as soon as is practicable after the occurrence of such Force Majeure Event. The Party claiming force majeure shall notify the other Party with notice of the Force Majeure Event as soon as practicable, but in no event later than fourteen (14) days after its occurrence, which notice shall reasonably identify such obligations under this Agreement and the extent to which performance thereof will be affected. In such event, the Parties shall meet promptly to determine an equitable solution to the effects of any such Force Majeure Event.

14.16. Non-Use of MIT Name. Neither Sandoz nor its Affiliates shall use the name of "MIT," "Lincoln Laboratory" or any variation, adaptation, or abbreviation thereof, or of any of its trustees, officers, faculty, students, employees, or agents (collectively, "MIT Associates"), or

any trademark owned by MIT, or any terms of the MIT Agreement, in any promotional material or other public announcement or disclosure without the prior written consent of MIT, or in the case of the name of any MIT Associate, the written consent of such MIT Associate. The immediately preceding sentence notwithstanding, without the consent of MIT (but subject to the provisions of Article 10), Sandoz and its Affiliates may state that they are sublicensed by MIT under one or more of the applicable Momenta Patent Rights, may make statements of facts, and may make disclosures or statements required by law.

14.17. Headings. The captions or headings of the Sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and are not part of the agreement of the parties and shall have no effect on the meaning of the provisions hereof. All references in this Agreement to Sections and Schedules are to sections and schedules to this Agreement, unless otherwise indicated.

14.18. Key Person Life Insurance. Sandoz may, at its option and sole expense, secure life insurance policies, naming Sandoz as the beneficiary, with respect to any principal scientist of Momenta. Momenta shall, at Sandoz's expense, reasonably cooperate with Sandoz's attempts to secure such life insurance policies.

14.19. No Consequential Damages. UNLESS RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR FROM A PARTY'S BREACH OF ARTICLE 10, NO PARTY HERETO WILL BE LIABLE TO ANY OTHER PARTY OR ITS AFFILIATES FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS SECTION 14.19 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER THIS AGREEMENT.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties have executed this Collaboration and License Agreement in counterparts, effective as of the 1st day of November, 2003.

MOMENTA PHARMACEUTICALS, INC.		**GENEVA PHARMACEUTICALS, INC.**	
By:	/s/Alan Crane	By:	[illegible]
Name	Alan Crane	Name:	
Title:	CEO	Title:	Vice President, Bus. Dev.

BIOCHEMIE WEST INDIES, N.V.
By: NOVARTIS INTERNATIONAL A.G., its Managing Director

By: [illegible]

Name:

Title:

By: SANDOZ GMBH, its Managaing Director

By: [illegible] [illegible]

Name:

Title: CFO General Counsel

Sandoz GmbH, a corporation organized under the laws of Austria, hereby guarantees the performance of the obligations of its subsidiary, Biochemie West Indies, N.V., under Sections 4.1, 4.2 and 4.3 of the Agreement.

SANDOZ GMBH

By: [illegible] [illegible]

Name:

Title: CFO General Counsel

SCHEDULE 1.22
PRE-EXISTING COSTS

Entity to Be Paid	**Payment Amount**	
[**]	U.S.$	[**]
[**]		[**]
[**]		[**]
[**]		[**]
[**]		[**]
[**]		Up to [**]
[**]		[**]
Approximate Total:	*U.S.$*	*[**]*

Note: The above payments exclude the following costs: $[**] to [**] (incurred through August 2003) and $[**] to [**] (incurred through August 2003), which are being or were paid solely by Momenta.

*Costs paid as of September 22, 2003. All other costs have been invoiced or committed. After the Effective Date, further payments will be due under the agreements with [**]and [**] and the anticipated agreement with [**]. With respect to [**], a portion of the up to $[**] will be for services conducted prior to the Effective Date and a portion of the up to $[**] will be for services conducted on or after the Effective Date. Invoices from [**] for a total of $[**] have been received to date for the month of September 2003.

**This is only the amount due on 11/01/03.

***Exact amount will be determined from invoices.

****This is only the amount due for initial equipment purchase.

SCHEDULE 1.48
CALCULATION OF MANUFACTURING COSTS

Manufacturing Cost with respect to a Party's or its Affiliates' cost to manufacture and/or Label the Product in finished form shall be calculated as the sum of [Actual Cost of Raw Materials] + [Actual Direct Labor Costs] + [Manufacturing Overhead Costs], where:

Actual Cost of Raw Materials. The Actual Cost of Raw Materials means: (a) the actual purchase unit cost of raw materials, including, without limitation, all starting materials, biological products, biological molecules, chemicals, precursors, intermediates, reagents, and active pharmaceutical ingredients; and (b) the actual purchase unit cost of packaging components necessary to manufacture or Label the Product, as the case may be; in each case of (a) and (b), multiplied by the actual quantity consumed in the production and manufacturing and/or Labeling process, as the case may be, including any usage or yield variances and any write-offs caused by expiration, obsolescence, accident and/or book-to-physical differences, and (c) all direct shipping costs to the manufacturer associated with (a) and (b) above.

Actual Direct Labor Costs. Actual Direct Labor Costs means the actual cost of direct labor (salary and benefits) to manufacture and/or Label the Product, including, without limitation, (a) any efficiency, activity and spending variances from standards; (b) material adjustments for off-grade or defective material, handling losses, physical adjustments, and salvage; and (c) shipment charges, including all direct costs of shipping from the Party's manufacturing and/or distribution facility to a Third Party Labeler and from such Third Party Labeler to such Party's destination facility.

Manufacturing Overhead Costs. Manufacturing Overhead Costs means the reasonable manufacturing overhead resources consumed in the manufacturing and production and/or Labeling process, as the case may be, of a specified quantity of the Product, which, with respect to any plant, except a plant, or a part of a plant, built exclusively for the manufacture of the Product, shall be based on the then-current Full Capacity of the relevant plant, rather than the actual level of demand throughput, and which shall include, without limitation: (a) normal depreciation of building, machinery, and equipment; and (b) plant management. "Full Capacity" means, (x) with respect to a plant operating at or below [**]% of its Entire Capacity, [**]% of the Entire Capacity, and (y) with respect to a plant operating above [**]% of its Entire Capacity, the actual demand throughput at which the plant is operating. "Entire Capacity" means production at [**] percent ([**]%), which shall not exclude any loss of capacity resulting from planned maintenance.

For the sake of clarity, and by way of examples, (1) if a plant is operating at [**]% of its Entire Capacity, and [**]% percent of the plant's Entire Capacity is devoted to the manufacture of the Product, [**]% ([**]) of the plant's overhead shall be allocated to the Product, and (2) if a plant is operating at [**]% of its Entire Capacity and [**]% of the plant's Entire Capacity is devoted to the manufacture of the Product, [**]% ([**]) of the plant's overhead shall be allocated to the Product.

SCHEDULE 1.58
CURRENT MOMENTA PATENT RIGHTS

Patent Rights [**] (licensed to Momenta by MIT in accordance with the MIT Agreement):

I. United States Patents and Applications

M.I.T. Case NO[**]
Entitled: [**]

[**]

USA Serial No. [**]

[**]

M.I.T. CASE NO. [**]
Entitled: [**]

USA Serial No. [**]
Entitled: [**]

M.I.T. CASE NO. 8448
Entitled: "Method for Identifying or Characterizing Properties of Polymeric Units"
By Nishla Keiser, Rahul Raman, Ram Sasisekharan, Zachary Shriver, and Ganesh Venkataraman

USA Patent No. 6,597,996, Issued July 22, 2003
Entitled: "Method for Identifying or Characterizing Properties of Polymeric Units"
Divisional Filed (see directly below)

USA Serial No. [**]
Entitled: [**]
[**]

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

USA Serial No. [**]
Entitled: [**]

M.I.T. Case No. [**] (in part as noted below)
Entitled: [**]
[**]

USA Serial No. [**]
Entitled: [**]
[**]

II. International (non-U.S.) Patents and Applications

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

EPC Application No. [**]
Entitled: [**]

Canada Application No. [**]
Entitled: [**]

Japanese Application No. [**]
Entitled: [**]

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

EPC Application No. [**]
Entitled: [**]

Canada Application No. [**]
Entitled: [**]

Japanese Application No. [**]
Entitled: [**]

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

PCT Application No. [**]
Entitled: [**]

M.I.T. Case No. [**] **(in part as noted below)**

Entitled: [**]
[**]

WO Application Serial No. [**]
Entitled: [**]

[**]

Patent Rights [**] ***(licensed to Momenta by MIT in accordance with the MIT Agreement):***

I. United States Patents and Applications

M.I.T. Case No. 5546
Entitled M.I.T. Case No. 5546, "The Heparinase Gene from Flavobacterium Heparinum", By Charles L. Cooney, Robert S. Langer, Jr., Kelley W. Moreman, and Ram Sasisekharan

USA Patent No. 5,714,376, Issued February 3, 1998
Entitled: "The Heparinase Gene from Flavobacterium Heparinum"

USA Patent No. 5,830,726, Issued November 3, 1998
Entitled: "Method for Obtaining a Modified Heparinase Gene"

M.I.T. Case No. 5981
Entitled: "Purification, Composition and Characterization of Heparinase II from Flavobacterium Heparinum"
By Charles L. Cooney, Robert S. Langer, Jr., Robert Lindhardt, Daniel Lohse, and Ram Sasisekharan

USA Patent No. 5,389,539, Issued February 14, 1995
Entitled: "Purification, Composition and Specificity of Heparinase I, II, and III from Flavobacterium Heparinum"

USA Patent No. 5,569,600, Issued October 29, 1996
Entitled: "Purification, Composition and Specificity of Heparinase I, II & III from Flavobacterium Heparinum"

II. International (non-U.S.) Patents and Applications

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

[**]

AT Patent No. [**]
BE Patent No. [**]
CH Patent No. [**]
DE Patent No. [**]
DK Patent No. [**]
ES Patent No. [**]
FR Patent No. [**]
GB Patent No. [**]
GR Patent No. [**]

IE Patent No. [**]
IT Patent No. [**]
LI Patent No. [**]
LU Patent No. [**]
MC Patent No. [**]
NL Patent No. [**]
SE Patent No. [**]
EP Patent No. [**]
All Entitled: [**]

CA Patent Application Serial No. [**]
Entitled: [**]

JP Patent Application Serial No. [**]
Entitled: [**]

M.I.T. Case No. [**]
Entitled [**]
[**]
EP Patent No. [**]
Entitled: [**]
CA Patent No. [**]
Entitled: [**]

JP Patent Application Serial No. [**]
Entitled: [**]

Patent Rights [**] ***(licensed to Momenta by MIT in accordance with the MIT Agreement):***

I. United States Patents and Applications

M.I.T. Case No. 6582
Entitled: "A Method for the Mass Spectrometric Determination of the Molecular Weight of Highly Acidic (and Basic) Organic and Biological Molecules"
By Klaus Biemann and Peter Juhasz

USA Patent No. 5,607,859, Issued March 4, 1997
Entitled: "Methods and Products for Mass Spectrometric Molecular Weight Determination of Polyionic Analytes Employing Polyionic Reagents"

Patent Rights Enzymes (licensed to Momenta by MIT in accordance with the MIT Agreement):

I. United States Patents and Applications

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

USA Serial No. [**]
[**]

M.I.T. Case No. [**]
Entitled: [**]
USA Serial No. [**]
Entitled: [**]

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

II. International (non-U.S.) Patents and Applications

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

PCT Application No. [**]
Entitled: [**]

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

JP Patent Application Serial No. [**]
Entitled: [**]

Momenta-Owned Patent Rights:

Entitled: [**]
[**]

US Application No. [**]
[**]

SCHEDULE 4.3
ADJUSTMENT SCHEDULE

A. Overview

The Parties agree that the Sandoz Parties shall have the right to offset Excess Costs against Commercial Milestone Payments, Profit Interest and royalties (whether paid pursuant to Sections 4.6.1, 4.7.1 or 4.8.1), to the extent, and subject to the limitations, set forth in this Schedule.

Definitions:

"Actual Momenta Economic Interest". Actual Momenta Economic Interest means, with respect to a Post-Launch Quarter, the percentage calculated in accordance with the following table:

Quarter	Actual Momenta Economic Interest
Each of the First Post-Launch Quarter through the [**] Post-Launch Quarter	The percentage calculated by dividing: (i) the sum of the [**] pursuant to this Schedule 4.3) during such Post-Launch Quarter and all preceding Post-Launch Quarters; by (ii) the [**] for such Post-Launch Quarter and all preceding Post-Launch Quarters
The [**] Post-Launch Quarter or any subsequent Post-Launch Quarter	The percentage calculated by dividing: (i) the sum of the [**] pursuant to this Schedule 4.3) for the [**] Post-Launch Quarter and any subsequent Post-Launch Quarters through the relevant Post-Launch Quarter; by (ii) the [**] for the [**] Post-Launch Quarter and any subsequent Post-Launch Quarters through the relevant Post-Launch Quarter

"Carryforward". Carryforward means that portion of Momenta Share of Excess Costs and True-Up Amounts that are not deductible from the Profit Interest or royalties (whether paid pursuant to Sections 4.6.1, 4.7.1 or 4.8.1), due to the provisions of subsection D of this Schedule 4.3, as shall be adjusted from time to time pursuant to subsections B.2 and C.3 of this Schedule 4.3.

"Economic Interest Variance". Economic Interest Variance means (a) with respect to the [**] Post-Launch Year, the difference between the Momenta Economic Interest for the Fourth Post-Launch Quarter and the Momenta Economic Interest for the First Post-Launch Quarter, and (b) with respect to the [**] through [**] Post-Launch Years, the difference between the Momenta Economic Interest for the last Post-Launch Quarter of such Post-Launch Year and the Momenta Economic Interest for the last Post-Launch Quarter of the previous Post-Launch Year.

"Momenta Economic Interest". Momenta Economic Interest means, with respect to a Post-Launch Quarter, the percentage calculated in accordance with the following table:

Quarter	Momenta Economic Interest
The [**] Post-Launch Quarter through the [**] Post-Launch Quarter, inclusive	The lesser of (a) the then-current Estimated Momenta Economic Interest of [**]% or (b) the Actual Momenta Economic Interest for the [**] Post-Launch Quarter
The [**] Post-Launch Quarter through the [**] Post-Launch Quarter, inclusive	The lesser of (a) the then-current Estimated Momenta Economic Interest of [**]% or (b) the Actual Momenta Economic Interest for the [**] Post-Launch Quarter
The [**] Post-Launch Quarter through the [**] Post-Launch Quarter, inclusive	The lesser of (a) the then-current Estimated Momenta Economic Interest of [**]% or (b) the Actual Momenta Economic Interest for the [**] Post-Launch Quarter
The [**] Post-Launch Quarter through the [**] Post-Launch Quarter, inclusive	The lesser of (a) the then-current Estimated Momenta Economic Interest of [**]% or (b) the Actual Momenta Economic Interest for the [**] Post-Launch Quarter
The [**] Post-Launch Quarter through the [**] Post-Launch Quarter, inclusive	The lesser of (a) the then-current Estimated Momenta Economic Interest of [**]% or (b) the Actual Momenta Economic Interest for the [**] Post-Launch Quarter
The [**] Post-Launch Quarter	The lesser of (a) the then-current Estimated Momenta Economic Interest of [**]% or (b) the Actual Momenta Economic Interest for the [**]Post-Launch Quarter
The [**] through the [**] Post-Launch Quarter, inclusive	The Actual Momenta Economic Interest for the [**] Post-Launch Quarter
The [**] Post-Launch Quarter in the [**]and every subsequent Post-Launch Years	The Actual Momenta Economic Interest for the [**] Post-Launch Quarter in such Post-Launch Year
Each of the [**] Post-Launch Quarters in the [**] and every subsequent Post-Launch Years	The Actual Momenta Economic Interest for the [**] Post-Launch Quarter in the prior Post-Launch Year

"Momenta Share of Excess Costs". Momenta Share of Excess Costs means, with respect to a Post-Launch Quarter, the product of the New Excess Costs for such Post-Launch Quarter

multiplied by the Momenta Economic Interest for such Post-Launch Quarter, as shall be adjusted from time to time pursuant to subsections B.2 and C.2 of this Schedule 4.3.

"New Excess Costs". New Excess Costs means (a) with respect to the [**] Post-Launch Quarter, the sum of any Excess Costs which were incurred during the [**] Post-Launch Quarter and all Excess Costs which were incurred prior to the [**] Post-Launch Quarter, and (b) with respect to any subsequent Post-Launch Quarter, any Excess Costs which were incurred during such Post-Launch Quarter.

"True-Up Amount". True-Up Amount means with respect to each of the [**]through the [**] Post-Launch Years, an amount equal to the product of the Economic Interest Variance for such Post-Launch Year multiplied by the sum of the New Excess Costs for the [**] Post-Launch Quarter and each additional Post-Launch Quarter thereafter, through the [**] Post-Launch Quarter in such Post-Launch Year.

Operative Provisions:

B. Offsets Against Commercial Milestone Payments

1. Sandoz's [**]% Profit Minimum. The Commercial Milestone Payment(s) shall be the lesser of (a) the Full Milestone Payment(s) which is to be made (in accordance with the timing in Section 4.10.2(b) for an applicable Milestone Payment Quarter, or (b) the remainder after (i) the aggregate portions of Profits paid to Momenta (excluding the effects of subsections C and E of this Schedule 4.3) for all Post-Launch Quarters (including the then-current Milestone Payment Quarter) after the most recent prior Milestone Payment Quarter (or, if no prior Milestone Payment Quarter has occurred, all Post-Launch Quarters), are deducted from (ii) [**]percent ([**]%) of the aggregate Profits for all Post-Launch Quarters (including the then-current Milestone Payment Quarter) after the most recent prior Milestone Payment Quarter (or, if no prior Milestone Payment Quarter has occurred, all Post-Launch Quarters). *For example, if Final Legal Clearance is achieved prior to the [**] anniversary of the U.S. Launch and [**], and if Profits for the [**] Post-Launch Quarters are U.S.$[**], then Momenta's portion of the Profits would be U.S.$[**]. The Commercial Milestone Payment would be reduced to U.S. $[**] (i.e., the lesser of (a) U.S.$[**] or (b) U.S.$[**] (i.e., U.S.$[**] — U.S.$[**] ([**]% of the U.S.$[**] Profits minus the portion of Profits due to Momenta))).*

2. Carryforward and Momenta Share of Excess Costs Deduction. After the provisions of subsection B.1 of this Schedule 4.3 have been applied, if there are New Excess Costs with respect to the Milestone Payment Quarter or a Carryforward exists at the start of such Milestone Payment Quarter, then the amounts of the Carryforward and the Momenta Share of Excess Costs with respect to such Post-Launch Quarter shall first be applied to reduce the amount of the Commercial Milestone Payment to be paid by Sandoz, and any Carryforward or Momenta Share of Excess Costs remaining with respect to such Post-Launch Quarter after the applicable Milestone Payment(s) has been reduced to zero in accordance with this subsection B.2 shall then be applied in accordance with the provisions of subsection C of this Schedule 4.3.

C. Offsets Against Payments of Profit Interest and Royalties

1. Full Milestone Payment Deduction. If, pursuant to subsection B.1 of this Schedule 4.3, the Commercial Milestone Payment(s) to be paid in a Milestone Payment Quarter is equal to the applicable Full Milestone Payment(s), the Profit Interest for such Post-Launch Quarter shall be adjusted to equal the product of (a) [**] percent ([**]%) times (b) the remaining Profits after such Full Milestone Payment(s) are deducted from Profits in the U.S. Territory for the applicable Post-Launch Quarter.

2. New Excess Costs Deduction. If New Excess Costs exist with respect to a Post-Launch Quarter, and Sandoz does not exercise its right to terminate the Agreement pursuant to Section 11.5 (if applicable), then, to the extent any Momenta Share of Excess Costs were not applied in full to reduce the amount of the Commercial Milestone Payment(s) pursuant to subsection B.2 of this Schedule 4.3, the amount of any Profit Interest or royalties, as the case may be, otherwise payable to Momenta for such Post-Launch Quarter shall be reduced by the applicable Momenta Share of Excess Costs for such Post-Launch Quarter, subject to the provisions of subsection D of this Schedule 4.3.

3. Carryforward Deduction. If a Carryforward exists with respect to a Post-Launch Quarter, then, to the extent such Carryforward was not applied in full to reduce the amount of the Commercial Milestone Payment pursuant to subsection B.2 of this Schedule 4.3, the amount of any Profit Interest or royalties, as the case may be, otherwise payable to Momenta for such Post-Launch Quarter shall be reduced by the applicable remaining Carryforward, subject to the provisions of subsection D of this Schedule 4.3.

D. [**]% Reduction Floor

1. Deduction Limit. With respect to any Post-Launch Quarter, the deduction of the Momenta Share of Excess Costs for such Post-Launch Quarter, the Carryforward and the True-Up Amount for such Post-Launch Quarter, collectively, shall not reduce by more than [**]percent ([**]%) the portion of Profits otherwise payable to Momenta for such Post-Launch Quarter under Sections 4.5 or 4.8 or the royalties otherwise payable to Momenta for such Post-Launch Quarter under Sections 4.6, 4.7 or 4.8, as applicable, and any portion of the Momenta Share of Excess Costs for such Post-Launch Quarter or the True-Up Amount for such Post-Launch Quarter not deducted from Profits or royalties payable to Momenta as a result of such limitation shall be added to the Carryforward for subsequent Post-Launch Quarters.

E. Momenta Economic Interest True-Up.

1. Overpayment by Momenta. If the Economic Interest Variance for a Post-Launch Year is negative, then the Sandoz Parties shall pay to Momenta, within forty-five (45) days after the end of such Post-Launch Year, an amount equal to the absolute value of the True-Up Amount for such Post-Launch Year.

2. Underpayment by Momenta. If the Economic Interest Variance for a Post-Launch Year is positive, then, prior to the payment of any portion of Profits or the royalties to Momenta

with respect to the last Post-Launch Quarter in such Post-Launch Year, the True-Up Amount for such Post-Launch Year shall first be deducted from the portion of Profits or the royalties otherwise payable to Momenta for such last Post-Launch Quarter in such Post-Launch Year, subject to the provisions of subsection D of this Schedule 4.3.

F. Examples

The following examples are for illustrative purposes only. Any errors or omissions in this section should not be construed to change the meaning of the rest of this Schedule 4.3 or this Agreement. Figures 4.3(a) and 4.3(b) provide spreadsheets with calculations through the [**] Post-launch Year.

Assumptions. Net Sales, Manufacturing Costs, Selling Expenses, and New Excess Costs are as reported in Figures 4.3(a) and 4.3(b). It is assumed for this example that [**] until the beginning of the [**] Post-Launch Year (it is assumed that [**] as of the first day of the [**] Launch Year and is not [**]). It is also assumed that First Commercial Sale of the Product occurs part-way through the [**] Post-Launch Quarter. Finally, it is assumed that First Commercial Sale does not occur until after Final Legal Clearance in Figure 4.3(a), and that Final Legal Clearance occurs during the [**] Quarter of the [**] Post-Launch Year in Figure 4.3(b). All numbers are reported to two decimal points for ease of illustration and except as otherwise specified represent millions of US dollars.

Calculations for figure 4.3(a) (working column by column from left to right).

Profit. The total Profit is calculated by subtracting Manufacturing Costs and Selling Expenses from Net Sales.

Preliminary Profit/Royalty Calculation 1. The column entitled Preliminary Profit/Royalty Calculation 1 (taking into account only Net Sales, Manufacturing Costs, Selling Expenses and Third Party Competitor status), is calculated, based on the assumptions listed above, as [**]% of Profits until a Third Party Competitor exists at the beginning of the [**] Post-Launch Year, and then as tiered Post-[**] Royalty rates on Net Sales of [**]% and [**]%, as applicable.

Momenta Economic Interest. In the first [**] Post-Launch Years, the Momenta Economic Interest is calculated as the lesser of the Actual Momenta Economic Interest or the Estimated Momenta Economic Interest (as described in subsection A of this Schedule 4.3). As an example, Actual Momenta Economic Interest in the [**] Quarter of the [**] Post-Launch Year is calculated as follows. The sum of the Profit/Royalty payable to Momenta (as calculated in the previous column) for all Quarters from U.S. Launch through the [**] Quarter of the [**] Post-Launch Year ($[**]) is divided by the sum of the Profits for the Product over the same period ($[**]) to yield [**]%. Since this is less than the Estimated Momenta Economic Interest of [**]% for that same Quarter, the Momenta Economic Interest is [**]%. In the Sixth and subsequent Post-Launch Years, the Momenta Economic Interest is calculated as described in subsection A of this Schedule 4.3.

Commercial Milestone Payment. The first Commercial Milestone Payment in the illustration is reduced for two reasons. First, the Sandoz Parties' portion of Profits would be less than [**]% if the full $[**] Commercial Milestone Payment was made. Therefore, the Commercial Milestone is reduced as follows. [**]% of the Profits since the last Milestone Payment Quarter (or since U.S. Launch in this case, since it is the first Commercial Milestone Payment) is calculated. Here, the total Profits are $[**], and [**]% of the sum of such Profits for the [**] through the [**] Post-Launch Quarters is $[**]. From this [**]% of the $[**] in Profits is subtracted any Profit/royalty payments made to Momenta (excluding the effects of subsections C and E of this Schedule 4.3) during the same [**] Quarters (in this case, Profit payments, which total $[**]), resulting in $[**]. This $[**] is the Commercial Milestone Payment adjusted for the provision that ensures the Sandoz Parties' minimum [**]% Profit share (subsection B.1 of this Schedule 4.3). The first Commercial Milestone Payment is then further adjusted (as described in subsection B.2 of this Schedule 4.3) by subtracting $[**] for the Momenta Share of Excess Costs in that Quarter, resulting in a final adjusted Commercial Milestone Payment of $[**]. The second and third Commercial Milestone Payments do not require similar adjustments and are both $[**].

Preliminary Profit/Royalty Calculation 2. The Preliminary Profit/Royalty Calculation 2 in the next column now includes the impact of any deductions made as a result of the Commercial Milestone Payments. Note that the first Commercial Milestone Payment which is reduced due to the provision related to the Sandoz Parties' [**]% Profit minimum, as described above, is not subtracted in the Profit calculation (as described in subsection C of this Schedule 4.3). The second and third Commercial Milestone Payments, which are full $[**] payments, are subtracted.

Momenta Share of Excess Costs. Momenta Share of Excess Costs are calculated by multiplying New Excess Costs in the applicable Quarter by the applicable Momenta Economic Interest for that same Quarter.

True Up Amount. The True-Up Amount is calculated by multiplying the Economic Interest Variance by the sum of all previous Quarters' (but not including the current Quarter's) New Excess Costs. For example, in Q4 of the [**] Post-Launch Year, the Economic Interest Variance of [**]% ([**]%-[**]%) is multiplied by the sum of $[**], $[**], and $[**] (but not $[**]) to yield $[**].

Preliminary Profit/Royalty Calculation 3. The Preliminary Profit/Royalty Calculation 3 in the next column now takes into account both the Momenta Share of Excess Costs and the True-Up Amount. Note that in the [**] Post-launch Quarter, the Momenta Share of Excess Costs would reduce the payment by more than [**]%. Hence (as described in subsection D of this Schedule 4.3), the payment amount is only reduced here from $[**] to [**]% of this amount, or $[**] Thus only $[**] of the $[**] of the Momenta Share of Excess Costs is paid in this Quarter. The remaining $[**] becomes part of the Carryforward.

Carryforward and Final Profit/Royalty Calculation. Carryforwards are subtracted from the Preliminary Profit/Royalty Calculations 3 in the previous column to complete the Final Profit/Royalty Calculation.

Differences in calculations for Figure 4.3(b). Except as provided in this paragraph, the assumptions and calculations of Figure 4.3(a) apply to Figure 4.3(b). In Figure 4.3(b), Final Legal Clearance occurs during the first Quarter of the [**] Post-Launch Year. As a result, no Commercial Milestone Payments are made in the first Quarter of the [**] Post-Launch Year or in the first Quarter of the [**] Post-Launch Year. In the first Quarter of the [**] Post-Launch Year, the Momenta Share of Excess Costs is deducted from the Preliminary Profit/Royalty Calculation 2 rather than from the Commercial Milestone Payment. Finally, the Commercial Milestone Payment in Figure 4.3(b) is made in the Quarter that Final Legal Clearance occurs. The payment is calculated according to subsection B.1 of this Schedule 4.3. This payment is also subtracted from Profits to calculate the Preliminary Profit/Royalty 2 for the first Quarter of the [**] Post-Launch Year in accordance with subsection C.1 of this Schedule 4.3.

Figure 4.3(a) (page 1)

	Net Sales	Third Party Competitor	Manufacturing Costs	Selling Expenses	Profit (total for product)	Preliminary Profit/Royalty Calculation 1	Momenta Economic Interest	Commercial Milestone
Q1 Yr 1	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 1	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 1	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 1	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 2	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	[**]
Q2 Yr 2	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 2	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 2	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 3	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	[**]
Q2 Yr 3	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 3	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 3	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 4	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	[**]
Q2 Yr 4	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 4	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 4	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 5	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 5	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 5	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 5	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 6	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 6	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 6	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 6	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 7	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 7	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 7	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 7	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	

Figure 4.3(a) (page 2)

Preliminary Profit/Royalty Calculation 2	New Excess Costs	Momenta Share of Excess Costs	True Up	Preliminary Profit/Royalty Calculation 3	New Carryforward	Cummulative Carryforward	Final Profit/Royalty Calculation
[**]	[**]	[**]		[**]	[**]	[**]	[**]
[**]				[**]		[**]	[**]
[**]				[**]			[**]
[**]			[**]	[**]			[**]
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[**]				[**]			[**]
[**]				[**]			[**]
[**]				[**]			[**]
[**]				[**]			[**]

Figure 4.3(b) (page 1)

	Net Sales	Third Party Competitor	Manufacturing Costs	Selling Expenses	Profit (total for product)	Preliminary Profit/Royalty Calculation 1	Momenta Economic Interest	Commercial Milestone
Q1 Yr 1	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 1	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 1	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 1	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 2	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 2	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 2	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 2	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 3	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 3	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 3	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 3	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 4	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	[**]
Q2 Yr 4	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 4	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 4	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 5	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 5	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 5	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 5	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 6	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 6	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 6	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 6	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q1 Yr 7	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q2 Yr 7	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q3 Yr 7	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	
Q4 Yr 7	[**]	[**]	[**]	[**]	[**]	[**]	[**]%	

Figure 4.3(b) (page 2)

Preliminary Profit/Royalty Calculation 2	New Excess Costs	Momenta Share of Excess Costs	True Up	Preliminary Profit/Royalty Calculation 3	New Carryforward	Cummulative Carryforward	Final Profit/Royalty Calculation
[**]	[**]	[**]		[**]	[**]	[**]	[**]
[**]				[**]		[**]	[**]
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[**]				[**]			[**]

SCHEDULE 5.8

ANNUAL COLLABORATION PLAN:

Preliminary List of Activities and assignment of lead responsibility to Party(ies)

Functional Area	Activity	Lead
Technology / Characterization	Support [**] Complete [**] the Product Continue to [**] the Product approval	[**]
Regulatory	Prior to [**] the Product — Manage [**] — [**] the Product — manage [**] — submit [**] — [**]	[**] [**]
Pre-Clinical / Clinical	Design [**] the Product and Product commercialization	[**]
Manufacturing	[**] — research [**] — secure [**] — [**]process [**] — [**] and stability — [**] and stability — [**] support [**] — [**] stability — successful [**] — commercial [**] — commercial [**] [**] — [**] — [**] and stability — [**] and stability — [**] methods [**] — manage [**]	[**] [**] [**]
Legal	[**] — to support [**] Litigation	[**] [**]
Commercial	Pre-Launch Marketing Strategy and Plan Product Launch and Commercialization	[**]

S = Sandoz
M = Momenta
S/M = Lead to be defined between Sandoz or Momenta by JPT

Exhibit 31.1

CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

Dated: November 8, 2012

/s/ Craig A. Wheeler
Craig A. Wheeler
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

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

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

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

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

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

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

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

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

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

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

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

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

Dated: November 8, 2012

/s/ Richard P. Shea
Richard P. Shea
Senior Vice President and Chief Financial Officer

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Momenta Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Craig A. Wheeler, President and Chief Executive Officer of the Company, and Richard P. Shea, Senior Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, that:

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

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

Dated: November 8, 2012

/s/ Craig A. Wheeler
Craig A. Wheeler
President and Chief Executive Officer

Dated: November 8, 2012

/s/ Richard P. Shea
Richard P. Shea
Senior Vice President and Chief Financial Officer