MOMENTA PHARMACEUTICALS INC

FORM 10-Q
(Quarterly Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 March 31, 2017

or

☐ **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, smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of April 24, 2017 , there were 74,198,113 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

MOMENTA PHARMACEUTICALS, INC.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements contained in this Quarterly Report on Form 10-Q that are about future events or future results, or are otherwise not statements of 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 statements are based on current expectations, estimates, forecasts, projections, intentions, goals, strategies, plans, prospects and the beliefs and assumptions of our management. In some cases, these statements can be identified by words such as "anticipate," "approach," "believe," "can," "contemplate," "continue," "could," "ensure," "estimate," "expect," "goal," "intend," "likely," "may," "might," "objective," "opportunity," "plan," "potential", "predict," "project," "pursue," "seek," "schedule," "should," "strategy," "target," "typically," "will," "would," and other similar words or expressions, or the negative of these words or similar words or expressions. These statements include, but are not limited to, statements regarding our expectations regarding the development and utility of our products and product candidates; development, manufacture and commercialization of our products and product candidates; efforts to seek and manage relationships with collaboration partners, including without limitation for our biosimilar and novel therapeutic programs; the timing of clinical trials and the availability and timing of reporting results; the timing of launch of products and product candidates, including GLATOPA ® (glatiramer acetate injection) 40 mg/mL; GLATOPA market share, market potential and product revenues; the timing, merits, strategy, impact and outcome of, and decisions regarding, litigation and legal proceedings; collaboration revenues and research and development revenues; manufacturing, including statements regarding Sandoz' third party fill/finish manufacturer for GLATOPA, Pfizer Inc.; the FDA warning letter received by Sandoz' third party fill/finish manufacturer for GLATOPA, Pfizer Inc.; timing of regulatory filings, reviews and approvals, including the timing of the regulatory review and approval of the GLATOPA 40 mg/mL ANDA; the sufficiency of our current capital resources and projected milestone payments and product revenues for future operations; our future financial position, including but not limited to our future operating losses, our potential future profitability, our future expenses, the composition and mix of our cash, cash equivalents and marketable securities, our future revenues and our future liabilities; our funding transactions and our intended uses of proceeds thereof; Enoxaparin Sodium Injection product revenues and market potential; product candidate development costs; receipt of contingent milestone payments; accounting policies, estimates and judgments; our estimates regarding the fair value of our investment portfolio; the market risk of our cash equivalents, marketable securities, and derivative, foreign currency and other financial instruments; rights, obligations, terms, conditions and allocation of responsibilities and decision making under our collaboration agreements; the regulatory pathway for biosimilars; our strategy, including but not limited to our regulatory strategy, and scientific approach; the importance of key customer distribution arrangements; market potential and acceptance of our products and product candidates; future capital requirements; reliance on our collaboration partners and other third parties, including Sandoz' third party fill/finish manufacturer for GLATOPA, Pfizer Inc.; the competitive landscape; changes in, impact of and compliance with laws, rules and regulations; product reimbursement policies and trends; pricing of pharmaceutical products, including our products and product candidates; our stock price; our intellectual property strategy and position; sufficiency of insurance; attracting and retaining qualified personnel; our internal controls and procedures; acquisitions or investments in companies, products and technologies; entering into collaboration and/or license arrangements; marketing plans; financing our planned operating and capital expenditure; leasing additional facilities; materials used in our research and development; royalty rates; our collaborators' plans; and vesting of equity awards.

Any forward-looking statements in this Quarterly Report on Form 10-Q involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Important factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. "Risk Factors" and discussed elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

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

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 260,487	$ 150,738
Marketable securities	173,262	202,413
Collaboration receivable	26,544	70,242
Prepaid expenses and other current assets	9,185	4,607
Total current assets	469,478	428,000
Property and equipment, net	21,397	20,847
Restricted cash	21,761	21,761
Intangible assets, net	4,901	5,189
Other long-term assets	1,877	1,940
Total assets	$ 519,414	$ 477,737
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,062	$ 3,632
Accrued expenses	23,037	26,866
Collaboration advance	27,203	32,895
Deferred revenue	57,184	7,272
Other current liabilities	—	11
Total current liabilities	114,486	70,676
Deferred revenue, net of current portion	29,653	31,360
Other long-term liabilities	4,960	3,793
Total liabilities	149,099	105,829
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Common stock, $0.0001 par value per share; 100,000 shares authorized, 73,062 shares issued and 72,833 shares outstanding at March 31, 2017 and 71,305 shares issued and 71,076 outstanding at December 31, 2016	7	7
Additional paid-in capital	879,319	848,304
Accumulated other comprehensive income	20	86
Accumulated deficit	(505,917)	(473,375)
Treasury stock, at cost, 229 shares	(3,114)	(3,114)
Total stockholders' equity	370,315	371,908
Total liabilities and stockholders' equity	$ 519,414	$ 477,737

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

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

	Three Months Ended March 31,	
	2017	**2016**
Collaboration revenues:		
Product revenue	$ 23,404	$ 14,800
Research and development revenue	3,210	5,050
Total collaboration revenue	26,614	19,850
Operating expenses:		
Research and development	36,101	28,757
General and administrative	23,105	15,647
Total operating expenses	59,206	44,404
Operating loss	(32,592)	(24,554)
Other income	833	542
Net loss	$ (31,759)	$ (24,012)
Basic and diluted net loss per share	$ (0.46)	$ (0.35)
Weighted average shares used in computing basic and diluted net loss per share	69,711	68,285
Comprehensive loss:		
Net loss	$ (31,759)	$ (24,012)
Net unrealized holding (losses) gains on available-for-sale marketable securities	(66)	133
Comprehensive loss	$ (31,825)	$ (23,879)

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)

	Three Months Ended March 31,	
	2017	**2016**
Cash Flows from Operating Activities:		
Net loss	$ (31,759)	$ (24,012)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization of property and equipment	1,266	1,889
Share-based compensation expense	6,803	4,828
Amortization of premium on investments	37	290
Amortization of intangibles	288	265
Changes in operating assets and liabilities:		
Collaboration receivable	43,698	(557)
Prepaid expenses and other current assets	(506)	(926)
Other long-term assets	63	(730)
Accounts payable	3,438	(665)
Accrued expenses	(3,953)	(8,268)
Collaboration advance	(5,692)	—
Deferred revenue	48,205	41,636
Other current liabilities	(11)	(350)
Other long-term liabilities	1,167	523
Net cash provided by operating activities	63,044	13,923
Cash Flows from Investing Activities:		
Purchases of property and equipment	(1,700)	(1,540)
Purchases of marketable securities	(47,384)	(119,368)
Proceeds from maturities of marketable securities	76,432	134,397
Net cash provided by investing activities	27,348	13,489
Cash Flows from Financing Activities:		
Net proceeds from issuance of common stock under ATM facility	14,441	—
Proceeds from issuance of common stock under stock plans	4,916	558
Net cash provided by financing activities	19,357	558
Increase in cash and cash equivalents	109,749	27,970
Cash and cash equivalents, beginning of period	150,738	61,461
Cash and cash equivalents, end of period	$ 260,487	$ 89,431
Non-Cash Investing/Financing Activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 1,051	$ 102
Receivable due from broker for issuance of common stock under ATM facility	$ 4,072	$ —
Impact of adopting ASU 2016-09	$ 783	$ —

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 focused on developing generic versions of complex drugs, biosimilars and novel therapeutics for autoimmune diseases. The Company presently derives all of its revenue from its 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, 2016 , 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 24, 2017. The year-end condensed consolidated 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 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.

Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists; services have been performed or products have been delivered; the fee is fixed or determinable; and collection is reasonably assured.

The Company has entered into collaboration and license agreements with pharmaceutical companies for the development and commercialization of certain of its product candidates. The Company's performance obligations under the terms of these agreements may include (i) transfer of intellectual property rights (licenses), (ii) providing research and development services, and (iii) participation on joint steering committees with the collaborators. Non-refundable payments to the Company under these agreements may include up-front license fees, payments for research and development activities, payments based upon the achievement of defined collaboration objectives and profit share or royalties on product sales.

At March 31, 2017 , the Company had collaboration and license agreements with Sandoz AG (formerly Sandoz N.V. and Biochemie West Indies, N.V.), an affiliate of Novartis Pharma AG, and Sandoz Inc. (formerly Geneva Pharmaceuticals, Inc.), collectively referred to as Sandoz; Sandoz AG; Mylan Ireland Limited, a wholly-owned, indirect subsidiary of Mylan N.V., or Mylan; and CSL Behring Recombinant Facility AG, or CSL, a wholly-owned indirect subsidiary of CSL Limited.

The Company evaluates multiple element agreements under the Financial Accounting Standards Board's, or FASB, Accounting Standards Update, or ASU, No. 2009-13, Multiple-Deliverable Revenue Arrangements, or ASU 2009-13. When evaluating multiple element arrangements under ASU 2009-13, the Company identifies the deliverables included within the agreement and determines whether the deliverables under the arrangement represent separate units of accounting. Deliverables under the arrangement are a separate unit of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item and delivery or performance of the undelivered items are considered probable and substantially within the Company's control. This evaluation requires subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have standalone value, based on the consideration of the relevant facts and circumstances for each arrangement. The Company considers whether the collaborator can use the license or other deliverables for their intended purpose without the receipt of the remaining elements, and whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered items.

Arrangement consideration generally includes up-front license fees and non-substantive options to purchase additional products or services. The Company determines how to allocate arrangement consideration to identified units of accounting based on the selling price hierarchy provided under the relevant guidance. The Company determines the estimated selling price for deliverables using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or best estimate of selling price, or BESP, if neither VSOE nor TPE is available. Determining the BESP for a deliverable requires significant judgment. The Company uses BESP to estimate the selling price for licenses to the Company's proprietary technology, since the Company often does not have VSOE or TPE of selling price for these deliverables. In those circumstances where the Company utilizes BESP to determine the estimated selling price of a license to the Company's proprietary technology, the Company considers entity specific factors, including those factors contemplated in negotiating the agreements as well as the license fees negotiated in similar license arrangements. Management may be required to exercise considerable judgment in estimating the selling prices of identified units of accounting under its agreements. In validating the Company's BESP, the Company evaluates whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple deliverables.

Up-Front License Fees

Up-front payments received in connection with licenses of the Company's technology rights are deferred if facts and circumstances dictate that the license does not have stand-alone value. When management believes the license to its intellectual property does not have stand-alone value from the other deliverables to be provided in the arrangement, it is combined with other deliverables and the revenue of the combined unit of accounting is recorded based on the method appropriate for the last delivered item. The Company recognizes revenue from non-refundable, up-front license fees either when the final deliverable is delivered to the customer or on a straight-line basis over the contracted or estimated period of performance if there are multiple deliverables that are satisfied over time. Accordingly, the Company is required to make estimates regarding the development timelines for product candidates being developed pursuant to any applicable agreement. The determination of the length of the period over which to recognize the revenue is subject to judgment and estimation and can have an impact on the amount of revenue recognized in a given period. Quarterly, the Company reassesses its period of substantial involvement over which the Company amortizes its up-front license fees and makes adjustments as appropriate. The Company's estimates regarding the period of performance under its collaborative research and development and licensing agreements have changed in the past and may change in the future. Any change in the Company's estimates could result in changes to the Company's results for the period over which the revenues from an up-front license fee are recognized.

Milestones

At the inception of each arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive, in accordance with ASU No. 2010-17, Revenue Recognition—Milestone Method. A milestone is defined as an event that can only be achieved based on the Company's performance, and there is substantive uncertainty about whether the event will be achieved at the inception of the arrangement. Events that are contingent only on the passage of time or only on counterparty performance are not considered milestones under accounting guidance. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the Company's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (b) the consideration relates solely to past performance (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement and (d) the milestone fee is refundable or adjusts based on future performance or non-performance. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in

the arrangement in making this assessment. Payments that are contingent upon the achievement of a substantive milestone are recognized in their entirety in the period in which the milestone is achieved, assuming all other revenue recognition criteria are met.

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.

Profit Share on Sandoz' Sales of Enoxaparin Sodium Injection ® and GLATOPA ®

Profit share revenue is reported as product revenue and is recognized based upon contractual profit of licensed products in licensed territories in the period the sales occur as provided by the collaboration agreement. The amount of net sales and contractual profit is determined based on amounts provided by the collaborator and involve the use of estimates and judgments, such as product sales allowances and accruals related to prompt payment discounts, chargebacks, governmental and other rebates, distributor, wholesaler and group purchasing organizations fees, product returns, and co-payment assistance costs, which could be adjusted based on actual results in the future. The Company is highly dependent on its collaborators for timely and accurate information regarding any net revenues realized from sales of Enoxaparin Sodium Injection and GLATOPA in order to accurately report its results of operations.

Research and Development Revenue under Collaborations with Sandoz

Under its collaborations with Sandoz, the Company is reimbursed at a contractual full-time equivalent, or FTE, rate for any FTE employee expenses as well as any external costs incurred for commercial and related activities. The Company recognizes research and development revenue from FTE services and external costs upon completion of the performance requirements (i.e., as the services are performed and the reimbursable costs are incurred). Revenues are recorded on a gross basis as the Company contracts directly with, manages the work of and is responsible for payments to third-party vendors for such commercial and related services.

Collaboration Receivable

Collaboration receivable represents:

- Amounts due to the Company for its contractual profit share on Sandoz' sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL;
- Amounts due to the Company for reimbursement of research and development services and external costs under the collaboration with Sandoz and, where applicable, the former collaboration with Baxalta;
- Amounts due from Mylan for its 50% share of certain collaboration expenses under the cost-sharing provisions of the Mylan Collaboration Agreement that are not funded through the continuation payments; and
- As of December 31, 2016 , the $51.2 million asset return payment due from Baxalta, as discussed in Note 5, *Collaborations and License Agreements* . In January 2017, the Company received the $51.2 million payment from Baxalta.

The Company has not recorded any allowance for uncollectible accounts or bad debt write-offs and it monitors its receivables to facilitate timely payment.

Collaboration Advance

Collaboration advance represents payments received from Mylan that will be applied to amounts due from Mylan in future periods for the funding of Mylan's 50% share of certain collaboration expenses under the cost-sharing provisions of the Mylan Collaboration Agreement.

Deferred Revenue

Deferred revenue represents consideration received from collaborators in advance of achieving certain criteria that must be met for revenue to be recognized in conformity with GAAP.

Adoption of ASU No. 2016-09

On January 1, 2017, the Company adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting and made an entity-wide accounting policy election to account for award forfeitures as they occur. As a result, the Company recorded a cumulative opening adjustment to accumulated deficit and additional paid-in capital of $0.8 million . The amended guidance also eliminates the requirement that excess tax benefits be realized as a reduction in current taxes payable before the associated tax benefit can be recognized in additional paid-in capital. This created approximately $5.3 million of deferred tax assets relating to federal and state net operating losses that are fully offset by a corresponding increase in the valuation allowance. As a result, there was no cumulative effect adjustment to accumulated deficit.

Net Loss Per Common Share

The Company computes basic net loss per common share by dividing net loss by the weighted average number of common shares outstanding, which includes common stock issued and outstanding and excludes unvested shares of restricted stock awards and units. The Company computes diluted net loss per common share by dividing net loss by the weighted average number of common shares and potential shares from outstanding stock options and unvested restricted stock awards and units determined by applying the treasury stock method.

The following table presents anti-dilutive shares for the three months ended March 31, 2017 and 2016 (in thousands):

	Three Months Ended March 31,	
	2017	**2016**
Weighted-average anti-dilutive shares related to:		
Outstanding stock options	3,761	6,659
Restricted stock awards	1,615	335

Since the Company had a net loss for all periods presented, the effect of all potentially dilutive securities is anti-dilutive. Accordingly, basic and diluted net loss per share is the same for the three months ended March 31, 2017 and 2016 . Anti-dilutive shares comprise the impact of the 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, approximately 1.4 million of performance-based restricted common stock awards that were granted between April 13, 2016 and March 31, 2017 had not vested as of March 31, 2017 , and were excluded from diluted shares outstanding as the vesting conditions for the awards, discussed further in Note 6 “ *Share-Based Payments - Restricted Stock Awards* ,” had not been met as of March 31, 2017 .

Fair Value Measurements

The tables below present information about the Company’s assets that are regularly measured and carried at fair value as of March 31, 2017 and December 31, 2016 , and indicate the level within the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

Description	**Balance as of March 31, 2017**	**Quoted Prices in Active Markets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Other Unobservable Inputs (Level 3)**
Assets:				
Cash equivalents:				
Money market funds and overnight repurchase agreements	$ 252,580	$ 223,580	$ 29,000	$ —
Marketable securities:				
Corporate debt securities	52,900	—	52,900	—
Commercial paper obligations	86,063	—	86,063	—
Asset-backed securities	34,299	—	34,299	—
Total	$ 425,842	$ 223,580	$ 202,262	$ —

Description	Balance as of December 31, 2016	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Other Unobservable Inputs (Level 3)
Assets:				
Cash equivalents:				
Money market funds and overnight repurchase agreements	$ 145,510	$ 121,510	$ 24,000	$ —
Marketable securities:				
Corporate debt securities	47,906	—	47,906	—
Commercial paper obligations	84,436	—	84,436	—
Asset-backed securities	70,071	—	70,071	—
Total	$ 347,923	$ 121,510	$ 226,413	$ —

The Company held $29 million and $24 million in overnight repurchase agreements as of March 31, 2017 and December 31, 2016 , respectively. The instruments are classified as Level 2 due to the collateral including both U.S. government-sponsored enterprise securities and treasury instruments.

There have been no impairments of the Company's assets measured and carried at fair value during the three months ended March 31, 2017 and 2016 . In addition, there were no changes in valuation techniques or transfers between the fair value measurement levels during the three months ended March 31, 2017 . The fair value of Level 2 instruments classified as marketable securities were determined through third party pricing services. For a description of the Company's validation procedures related to prices provided by third party pricing services, refer to Note 2 " *Summary of Significant Accounting Policies: Fair Value Measurements* " to the Company's consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2016 . The carrying amounts reflected in the Company's consolidated balance sheets for cash, collaboration receivable, 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's cash equivalents are composed of money market funds and overnight repurchase agreements. Money market funds are carried at fair value, which approximate cost at March 31, 2017 and December 31, 2016 . Overnight repurchase agreement yields are comparable to money market funds where principal and interest on the instruments is due the next day.

The Company classifies corporate debt securities, commercial paper and asset-backed securities as short-term and long-term marketable securities in its consolidated financial statements. See Note 2 " *Summary of Significant Accounting Policies: Cash, Cash Equivalents and Marketable Securities* " in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of the Company's accounting policies.

The following tables summarize the Company's cash, cash equivalents and marketable securities as of March 31, 2017 and December 31, 2016 (in thousands):

As of March 31, 2017	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, money market funds and overnight repurchase agreements	$ 260,487	$ —	$ —	$ 260,487
Corporate debt securities due in one year or less	52,932	—	(32)	52,900
Commercial paper obligations due in one year or less	86,000	63	—	86,063
Asset-backed securities due in one year or less	34,310	—	(11)	34,299
Total	$ 433,729	$ 63	$ (43)	$ 433,749
Reported as:				
Cash and cash equivalents	$ 260,487	$ —	$ —	$ 260,487
Marketable securities	173,242	63	(43)	173,262
Total	$ 433,729	$ 63	$ (43)	$ 433,749

As of December 31, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, money market funds and overnight repurchase agreements	$ 150,738	$ —	$ —	$ 150,738
Corporate debt securities due in one year or less	47,942	—	(36)	47,906
Commercial paper obligations due in one year or less	84,301	135	—	84,436
Asset-backed securities due in one year or less	70,084	1	(14)	70,071
Total	$ 353,065	$ 136	$ (50)	$ 353,151
Reported as:				
Cash and cash equivalents	$ 150,738	$ —	$ —	$ 150,738
Marketable securities	202,327	136	(50)	202,413
Total	$ 353,065	$ 136	$ (50)	$ 353,151

At March 31, 2017 and December 31, 2016 , the Company held 25 and 31 marketable securities, respectively, that were in a continuous unrealized loss position for less than one year. As the unrealized losses on these securities were caused by fluctuations in interest rates, the Company concluded that no other-than-temporary impairment exists with respect to these securities. At March 31, 2017 and December 31, 2016 , there were no securities in a continuous unrealized loss position for greater than one year. The Company believes the unrealized losses were caused by fluctuations in interest rates.

The following table summarizes the aggregate fair value of these securities as of March 31, 2017 and December 31, 2016 (in thousands):

	As of March 31, 2017		As of December 31, 2016	
	Aggregate Fair Value	Unrealized Losses	Aggregate Fair Value	Unrealized Losses
Corporate debt securities due in one year or less	$ 51,300	$ (32)	$ 47,906	$ (36)
Asset-backed securities due in one year or less	$ 34,299	$ (11)	$ 60,787	$ (14)

Treasury Stock

Treasury stock represents common stock currently owned by the Company as a result of shares withheld from the vesting of performance-based restricted common stock to satisfy minimum tax withholding requirements.

Comprehensive Income (Loss)

Comprehensive income (loss) is the change in equity of a company during a period from transactions and other events and circumstances, excluding transactions resulting from investments by owners and distributions to owners. Comprehensive income (loss) includes net (loss) income and the change in accumulated other comprehensive income (loss) for the period. Accumulated other comprehensive income (loss) consists entirely of unrealized gains and losses on available-for-sale marketable securities for all periods presented.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. The FASB has subsequently issued the following amendments to ASU 2014-09 which have the same effective date and transition date of January 1, 2018:

- In August 2015 the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which delayed the effective date of the new standard from January 1, 2017 to January 1, 2018. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date.

- In March 2016 the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, which clarifies the implementation guidance on principal versus agent considerations.

- In April 2016 the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance.

- In May 2016 the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients related to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers.

- In December 2016 the FASB issued ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers, which amends certain narrow aspects of the guidance issued in ASU No. 2014-09 including guidance related to the disclosure of remaining performance obligations and prior-period performance obligations, as well as other amendments to the guidance on loan guarantee fees, contract costs, refund liabilities, advertising costs and the clarification of certain examples.

The Company expects to adopt the new standard using the modified retrospective method as permissible under the transitional provisions of Topic 606 for all contracts not yet completed as of the effective date. The modified retrospective method applies the guidance retrospectively only to the most current period presented in the financial statements, recognizing the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings (or deficit) at the date of initial application. The Company is continuing to evaluate the potential impact that these standards will have on its financial position and results of operations.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for the Company on January 1, 2019. The Company is currently evaluating the impact of adopting this new accounting standard on its financial position and results of operations.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230), which simplifies certain elements of cash flow classification. The new guidance is intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. The ASU is effective for annual periods beginning after December 15, 2017. The Company is currently evaluating the impact the adoption of the ASU will have on its consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Restricted Cash, or ASU 2016-18. The amendments in ASU 2016-18 require an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows. ASU 2016-18 is effective for fiscal years, and interim periods within, beginning after December 15, 2017. Early adoption is permitted. A reporting entity must apply the amendments in ASU 2016-18 using a full retrospective approach. The Company is currently evaluating the impact the adoption of the ASU will have on its consolidated financial statements.

In January 2017, the FASB issued amended guidance related to business combinations. The amended guidance clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The new accounting guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. The Company early adopted this new guidance as of January 1, 2017 and will apply this new guidance to any future acquisitions.

3. Intangible Assets

Intangible assets consist solely of the core developed technology assets acquired from Parivid. See Note 6 " *Intangible Assets* " in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of the Parivid agreement.

The intangible assets are being amortized using the straight-line method over the estimated useful life of GLATOPA 20 mg/mL of approximately six years through June 2021. As of March 31, 2017 and December 31, 2016 , intangible assets, net of accumulated amortization, were as follows (in thousands):

	March 31, 2017			December 31, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value
Intangible assets	$ 13,617	$ (8,716)	$ 4,901	$ 13,617	$ (8,428)	$ 5,189

Amortization expense was approximately $0.3 million for each of the three months ended March 31, 2017 and 2016 .

The Company expects to incur amortization expense of approximately $1.2 million per year for the next four years and $0.3 million in the final year.

4. Restricted Cash

The Company designated $17.5 million as collateral for a security bond posted in the litigation against Amphastar, International Medical Systems, Ltd., a wholly owned subsidiary of Amphastar Pharmaceuticals, Inc. and Actavis, Inc. (formerly Watson Pharmaceuticals, Inc.). Additional information regarding the litigation is discussed within Note 8, *Commitments and Contingencies* . The $17.5 million is held in an escrow account by Hanover Insurance. The Company classified this restricted cash as long-term as the timing of a final decision in the Enoxaparin Sodium Injection patent litigation is not known.

The Company designated $2.4 million as collateral for a letter of credit related to the lease of office and laboratory space located at 675 West Kendall Street in Cambridge, Massachusetts. This balance will remain restricted through April 2018 and is therefore classified as non-current in the Company's consolidated balance sheet. The Company will earn interest on the balance.

The Company designated $0.7 million as collateral for a letter of credit related to the lease of office and laboratory space located at 320 Bent Street in Cambridge, Massachusetts. This balance will remain restricted through February 2027 and is therefore classified as non-current in the Company's consolidated balance sheet. The Company will earn interest on the balance.

The Company designated $1.1 million as collateral for a letter of credit related to the lease of office and laboratory space located at 301 Binney Street in Cambridge, Massachusetts. This balance will remain restricted through June 2025 and is therefore classified as non-current in the Company's consolidated balance sheet. The Company will earn interest on the balance.

5. Collaboration and License Agreements

At March 31, 2017 , the Company had collaboration and license agreements with Sandoz, Sandoz AG, Mylan and CSL. M923, the Company's biosimilar HUMIRA ® (adalimumab) candidate, was previously developed in collaboration with Baxalta under the Baxalta Collaboration Agreement, as defined below. The Baxalta Collaboration Agreement was terminated effective December 31, 2016 .

The Company records product revenue based on Sandoz' sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL.

Research and development revenue generally consists of amounts earned by the Company under its collaborations for technical development, regulatory and commercial milestones; reimbursement of research and development services and reimbursement of development costs under its collaborative arrangements; and recognition of the arrangement consideration.

The collaboration with Mylan is a cost-sharing arrangement pursuant to which reimbursement for Mylan's 50% share of collaboration expenses is recorded as a reduction to research and development expense and general and administrative expense depending on the nature of the activities.

The following tables provide amounts by period indicated and by line item included in the Company's accompanying condensed consolidated statements of operations and comprehensive loss attributable to transactions arising from its significant collaborative arrangements and all other arrangements, as defined in the FASB's Accounting Standards Codification Topic 808, *Collaborative Arrangements* .

The amounts in operating expenses generally represent external expenditures, including amortization of an intangible asset, and exclude salaries and benefits, share-based compensation, facilities, depreciation and laboratory supplies, as the majority of such costs are not directly charged to programs. The dollar amounts in the tables below are in thousands.

	For the Three Months Ended March 31, 2017			
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Mylan Collaboration Agreement (1)	Total Collaborations
Collaboration revenues:				
Product revenue	$ —	$ 23,404	$ —	$ 23,404
Research and development revenue:				
Recognition of upfront payments	—	—	1,796	1,796
Research and development services and external costs	963	451	—	1,414
Total research and development revenue	$ 963	$ 451	$ 1,796	$ 3,210
Total collaboration revenues	$ 963	$ 23,855	$ 1,796	$ 26,614
Operating expenses:				
Research and development expense	$ 1,526	$ 265	$ 7,053	$ 8,844
General and administrative expense	$ 4,550	$ 24	$ 357	$ 4,931
Total operating expenses	$ 6,076	$ 289	$ 7,410	$ 13,775

	For the Three Months Ended March 31, 2016				
	2003 Sandoz Collaboration Agreement	2006 Sandoz Collaboration Agreement	Mylan Collaboration Agreement (1)	Baxalta Collaboration Agreement (2)	Total Collaborations
Collaboration revenues:					
Product revenue	$ —	$ 14,800	$ —	$ —	$ 14,800
Research and development revenue:					
Recognition of upfront payments	—	—	922	2,442	3,364
Research and development services and external costs	77	645	—	964	1,686
Total research and development revenue	$ 77	$ 645	$ 922	$ 3,406	$ 5,050
Total collaboration revenues	$ 77	$ 15,445	$ 922	$ 3,406	$ 19,850
Operating expenses:					
Research and development expense	$ —	$ 293	$ 3,680	$ 314	$ 4,287
General and administrative expense	$ 1,064	$ 95	$ 112	$ 282	$ 1,553
Total operating expenses	$ 1,064	$ 388	$ 3,792	$ 596	$ 5,840

(1) The Mylan Collaboration Agreement, as defined below, became effective on February 9, 2016. As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, the Company offset approximately $5.5 million and $3.7 million against research and development costs and $0.2 million and $0.1 million against general and administrative costs during the three months ended March 31, 2017 and March 31, 2016 , respectively.
(2) The Baxalta Collaboration Agreement was terminated effective December 31, 2016 .

2003 Sandoz Collaboration Agreement

In 2003, the Company entered into a collaboration and license agreement, or the 2003 Sandoz Collaboration Agreement, with Sandoz to jointly develop, manufacture and commercialize Enoxaparin Sodium Injection, a generic version of LOVENOX ® , in the United States. Under the terms of the 2003 Sandoz Collaboration Agreement, the Company and Sandoz agreed to exclusively work with each other to develop and commercialize Enoxaparin Sodium Injection for any and all medical indications within the United States. In addition, the Company granted Sandoz an exclusive license under its intellectual property rights to develop and commercialize injectable enoxaparin for all medical indications within the United States.

Sandoz began selling Enoxaparin Sodium Injection in July 2010. In June 2015, the Company and Sandoz amended the 2003 Sandoz Collaboration Agreement, effective April 1, 2015, to provide that Sandoz would pay the Company 50% of contractually-defined profits on sales. Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the three months ended March 31, 2017 and 2016 , and therefore the Company recorded no product revenue for Enoxaparin Sodium Injection in those periods. The Company recognized research and development revenue from FTE services and external costs of $1.0 million and $0.1 million in the three months ended March 31, 2017 and 2016 , respectively.

2006 Sandoz Collaboration Agreement

In 2006 and 2007, the Company entered into a series of agreements, including a collaboration and license agreement, as amended, or the 2006 Sandoz Collaboration Agreement, with Sandoz AG; and a stock purchase agreement and an investor rights agreement, with Novartis Pharma AG. Under the 2006 Sandoz Collaboration Agreement, the Company and Sandoz AG agreed to exclusively collaborate on the development and commercialization of GLATOPA, among other products. 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. For GLATOPA, the Company is generally responsible for all of the development costs in the United States. For GLATOPA outside of the United States, the Company shares development costs in proportion to its profit sharing interest. The Company is reimbursed at a contractual FTE rate for any FTE employee expenses as well as any external costs incurred in the development of products to the extent development costs are borne by Sandoz. All commercialization costs are borne by Sandoz.

The term of the 2006 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 2006 Sandoz Collaboration Agreement. The 2006 Sandoz Collaboration Agreement may be terminated if either party breaches the

2006 Sandoz Collaboration Agreement or files for bankruptcy. In addition, either the Company or Sandoz may terminate the 2006 Sandoz Collaboration Agreement with respect to GLATOPA 40 mg/mL, if clinical trials are required for regulatory approval of GLATOPA 40 mg/mL.

Sandoz commenced sales of GLATOPA 20 mg/mL in the United States on June 18, 2015. Under the 2006 Sandoz Collaboration Agreement, the Company earns 50% of contractually-defined profits on Sandoz' worldwide net sales of GLATOPA 20 mg/mL. The Company is entitled to earn 50% of contractually-defined profits on Sandoz' worldwide net sales of GLATOPA 40 mg/mL, if and when GLATOPA 40 mg/mL is commercialized. Profits on net sales of GLATOPA are calculated by deducting from net sales the costs of goods sold and an allowance for selling, general and administrative costs, which is a contractual percentage of net sales. With respect to GLATOPA, Sandoz is responsible for funding all of the legal expenses incurred under the 2006 Sandoz Collaboration Agreement, except for FTE costs with respect to certain legal activities for GLATOPA; however a portion of certain legal expenses, including any patent infringement damages, can be offset against the profit-sharing amounts in proportion to the Company's 50% profit sharing interest.

For the three months ended March 31, 2017 , the Company recorded $23.4 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL. The Company recognized research and development revenue from FTE services and external costs of $0.5 million and $0.6 million in the three months ended March 31, 2017 and 2016 , respectively. The Company is eligible to receive in the aggregate up to $120 million in additional milestone payments upon the achievement of certain commercial and sales-based milestones for GLATOPA in the United States. None of these payments, once received, is refundable and there are no general rights of return in the arrangement. 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.

Baxalta Collaboration Agreement

The Company and Baxter International, Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (or collectively referred to as Baxter) entered into a global collaboration and license agreement, or the Baxter Collaboration Agreement, effective February 2012, to develop and commercialize biosimilars, including M923. In connection with Baxter's internal corporate restructuring in July 2015, Baxter assigned the Baxter Collaboration Agreement to Baxalta U.S. Inc., Baxalta GmbH and Baxalta Incorporated, collectively referred to as Baxalta. Subsequent to the assignment, the Company refers to "Baxter" as "Baxalta" and the "Baxter Collaboration Agreement" as the "Baxalta Collaboration Agreement." On June 3, 2016, Baxalta Incorporated and Shire plc, or Shire, announced the completion of the combination of Baxalta Incorporated and Shire. As a result of the combination, Baxalta Incorporated, of which Baxalta US Inc. and Baxalta GmbH are wholly-owned subsidiaries, is a wholly-owned subsidiary of Shire. On September 27, 2016, Baxalta gave the Company twelve months ' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement. On December 31, 2016 , the Company and Baxalta entered into an asset return and termination agreement, or the Baxalta Termination Agreement, which amended certain termination provisions of the Baxalta Collaboration Agreement and made the termination of that agreement effective as of December 31, 2016 . Baxalta was relieved of its obligations to continue to perform activities for M923 after December 31, 2016 , except for certain on-going clinical and regulatory activities, the majority of which were completed in April 2017, and in January 2017, Baxalta paid the Company a one-time cash payment of $51.2 million representing the costs Baxalta would have incurred in performing the activities it would have performed under Baxalta Collaboration Agreement through the original termination date.

Mylan Collaboration Agreement

On January 8, 2016, the Company and Mylan entered into a collaboration agreement, or the Mylan Collaboration Agreement, which became effective on February 9, 2016, pursuant to which the Company and Mylan agreed to collaborate exclusively, on a worldwide basis, to develop, manufacture and commercialize six of the Company's biosimilar candidates, including M834.

Under the terms of the Mylan Collaboration Agreement, Mylan paid the Company a non-refundable upfront payment of $45 million . In addition, the Company and Mylan equally share costs (including development, manufacturing, commercialization and certain legal expenses) and profits (losses) with respect to such product candidates, with Mylan funding its share of collaboration expenses incurred by the Company, in part, through up to six contingent milestone payments, totaling up to $200 million across the six product candidates, two of which, totaling $60.0 million , the Company received in the year ended December 31, 2016 .

For each product candidate other than M834, at a specified stage of early development, the Company and Mylan will each decide, based on the product candidate's development progress and commercial considerations, whether to continue the

development, manufacture and commercialization of such product candidate under the collaboration or to terminate the collaboration with respect to such product candidate.

Under the Mylan Collaboration Agreement, the Company granted Mylan an exclusive license under the Company's intellectual property rights to develop, manufacture and commercialize the product candidates for all therapeutic indications, and Mylan granted the Company a co-exclusive license under Mylan's intellectual property rights for the Company to perform its development and manufacturing activities under the product work plans agreed by the parties, and to perform certain commercialization activities to be agreed by the joint steering committee for such product candidates if the Company exercises its co-commercialization option described below. The Company and Mylan established a joint steering committee consisting of an equal number of members from the Company and Mylan to oversee and manage the development, manufacture and commercialization of product candidates under the collaboration. Unless otherwise determined by the joint steering committee, it is anticipated that, in collaboration with the other party, (a) the Company will be primarily responsible for nonclinical development activities and initial clinical development activities for product candidates; additional (pivotal or Phase 3 equivalent) clinical development activities for M834; and regulatory activities for product candidates in the United States through regulatory approval; and (b) Mylan will be primarily responsible for additional (pivotal or Phase 3 equivalent) clinical development activities for product candidates other than M834; regulatory activities for the product candidates outside the United States; and regulatory activities for products in the United States after regulatory approval, when all marketing authorizations for the products in the United States will be transferred to Mylan. Mylan will commercialize any approved products, with the Company having an option to co-commercialize, in a supporting commercial role, any approved products in the United States. The joint steering committee is responsible for allocating responsibilities for other activities under the collaboration.

The term of the collaboration will continue throughout the development and commercialization of the product candidates, on a product-by-product and country-by-country basis, until development and commercialization by or on behalf of the Company and Mylan pursuant to the Mylan Collaboration Agreement has ceased for a continuous period of two years for a given product candidate in a given country, unless earlier terminated by either party pursuant to the terms of the Mylan Collaboration Agreement.

The Mylan Collaboration Agreement may be terminated by either party for breach by, or bankruptcy of, the other party; for its convenience; or for certain activities involving competing products or the challenge of certain patents. Other than in the case of a termination for convenience, the terminating party will have the right to continue the development, manufacture and commercialization of the terminated products in the terminated countries. In the case of a termination for convenience, the other party will have the right to continue. If a termination occurs, the licenses granted to the non-continuing party for the applicable product will terminate for the terminated country. Subject to certain terms and conditions, the party that has the right to continue the development or commercialization of a given product candidate may retain royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the applicable product in the country or countries for which termination applies.

In accordance with Topic 605, the Company identified the deliverables at the inception of the Mylan Collaboration Agreement. The deliverables were determined to include (i) six development and product licenses, for each of M834 and the five additional collaboration products, (ii) research and development services related to each of M834 and the five additional collaboration products and (iii) the Company's participation in the joint steering committee. The Company has determined that each of the license deliverables does not have stand-alone value apart from the related research and development services deliverables because (1) there are no other vendors selling similar, competing products on a stand-alone basis, (2) Mylan does not have the contractual right to resell the license, and (3) Mylan 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 with respect to this arrangement, separate units of accounting exist for each of the six licenses together with the related research and development services, or the combined units of accounting, as well as a separate unit of accounting for participation in the joint steering committee. VSOE and TPE were not available for the combined units of accounting. As such, the Company determined BESP for the combined units of accounting based on an analysis of its existing license arrangements and other available data and the nature and extent of the research and development services to be performed. BESP for the joint steering committee unit of accounting was based on market rates for similar services. At the inception of the Mylan Collaboration Agreement, total arrangement consideration of $45 million was allocated to each of the units of accounting based on the relative selling price method. Of the $45 million , $8.2 million was allocated to the M834 combined unit of accounting, between $5.7 million and $9.0 million to the five additional combined units of accounting, considering the products' stage of development at the time the licenses were delivered, and $51,000 was allocated to the joint steering committee unit of accounting. Changes in the key assumptions used to determine BESP for the units of accounting would not have a significant effect on the allocation of arrangement consideration.

At the inception of the Mylan Collaboration Agreement, the Company delivered development and product licenses for all six collaboration products and commenced revenue recognition of the arrangement consideration allocated the respective units of accounting. In addition, the Company began revenue recognition for the arrangement consideration allocated to the joint steering committee unit of accounting. The Company is recording revenue on a straight-line basis over the applicable performance period during which the research and development services are expected to be delivered, which begins upon delivery of the development and product license and ends upon FDA approval of the product. The Company currently estimates that the performance period for the M834 unit of accounting is approximately five years , an average of approximately seven years for the additional five combined units of accounting and approximately eight years for the joint steering committee unit of accounting. As of March 31, 2017 , $36.9 million was deferred under this agreement, of which $7.2 million was included in current liabilities and $29.7 million was included in non-current liabilities in the consolidated balance sheet.

The Company and Mylan share collaboration expenses under the Mylan Collaboration Agreement. Collaboration costs incurred by the Company are recorded as research and development expense and/or general and administrative expense, depending on the nature of the activities, as incurred. Mylan's share of collaboration expenses is recorded as a collaboration receivable or collaboration advance in the consolidated balance sheet and a reduction in research and development and/or general and administrative expenses in the consolidated statements of operations and comprehensive loss, in accordance with the Company’s policy, which is consistent with the nature of the cost reimbursement.

Mylan will initially fund a portion of its 50% share of collaboration expenses through contingent milestone payments of up to $200 million across the six product candidates and any unused portion of the contingent payment(s) will be available to offset Mylan’s 50% share of future collaboration costs. If in a given year a contingent payment is not expected to be made by Mylan and there is no balance available from a prior contingent payment balance as of the beginning of the collaboration year, the parties will reconcile total collaboration expenses on a semi-annual basis and Mylan will make a payment to the Company. During the year ended December 31, 2016, the Company received two milestone payments totaling $60 million , of which $27.2 million will be applied toward the funding of Mylan's 50% share of certain collaboration expenses to be incurred in 2017 and is included in collaboration advance in the Company's consolidated balance sheet. The Company is eligible to receive up to $140 million in additional contingent milestone payments from Mylan, of which the Company expects to receive $35 million in 2017.

CSL License and Option Agreement

On January 5, 2017, the Company and CSL Behring Recombinant Facility AG, or CSL, a wholly-owned indirect subsidiary of CSL Limited, entered into a License and Option Agreement, or the CSL License Agreement, which became effective on February 17, 2017, pursuant to which the Company granted CSL an exclusive worldwide license to research, develop, and commercialize the Company’s M230 pre-clinical product candidate, an Fc multimer protein that is a selective immunomodulator of the Fc receptor. The CSL License Agreement also provides, on an exclusive basis, for the Company and CSL to conduct research on other Fc multimer proteins, and provides CSL the right to develop and commercialize these additional research products globally.

Pursuant to the terms of the CSL License Agreement, CSL paid the Company a non-refundable upfront payment of $50 million . For the development and commercialization of M230, the Company is eligible to receive up to $ 550 million in contingent clinical, regulatory and sales milestone payments, and additional negotiated milestone payments for a named research stage product should that enter development. The Company is also entitled to sales-based royalty payments in percentages ranging from a mid-single digit to low-double digits for M230 and a named research stage product should that enter development and be commercialized, and royalties and development milestone payments to be negotiated for any other products developed under the CSL License Agreement. Sales milestones are based on aggregated sales across M230 and any other products developed under the CSL License Agreement. The Company also has the option to participate in a cost-and-profit sharing arrangement, under which the Company would fund 50% of global research and development costs and 50% of U.S. commercialization costs for all products developed pursuant to the CSL License Agreement, or the Co-Funded Products, in exchange for either a 50% share of U.S. profits or 30% share of U.S. profits, determined by the stage of development at which the Company makes such election. For Co-Funded Products, royalties remain payable for territories outside of the United States and milestone payments are reduced. The Company also has the right to opt-out of such arrangement at its sole discretion, which would result in milestone payments and royalties reverting to their pre-arrangement amounts. The Company also has the option to participate in the promotion of Co-Funded Products in the United States, subject to a co-promotion agreement to be negotiated with CSL.

Under the CSL License Agreement, the Company granted CSL an exclusive license under the Company’s intellectual property to research, develop, manufacture and commercialize product candidates for all therapeutic indications. CSL has granted the Company a non-exclusive, royalty-free license under CSL’s intellectual property for the Company’s research and

development activities pursuant to the CSL License Agreement and its commercialization activities under any co-promotion agreement with CSL.

The Company and CSL formed a joint steering committee consisting of an equal number of members from the Company and CSL, to facilitate the research, development, and commercialization of product candidates.

Unless earlier terminated, the term of the CSL License Agreement commences on the Effective Date and continues until the later of (i) the expiration of all payment obligations with respect to products under the CSL License Agreement, (ii) the Company is no longer co-funding development or commercialization of any products and (iii) the Company and CSL are not otherwise collaborating on the development and commercialization of products or product candidates. CSL may terminate the CSL License Agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. The Company may terminate the CSL License Agreement under certain circumstances related to the development of M230 and if no activities are being conducted under the CSL License Agreement. Either party may terminate the CSL License Agreement (i) on a product-by-product basis if certain patent challenges are made, (ii) on a product-by-product basis for material breaches, or (iii) due to the other party's bankruptcy. Upon termination of the CSL License Agreement, subject to certain exceptions, the licenses granted under the CSL License Agreement terminate. In addition, dependent upon the circumstances under which the CSL License Agreement is terminated, the Company or CSL has the right to continue the research, development, and commercialization of terminated products, including rights to certain data, for the continued development and sale of terminated products and, subject to certain limitations, obligations to make sales-based royalty payments to the other party.

CSL's obligations under the CSL License Agreement are guaranteed by its parent company, CSL Limited.

In accordance with ASC Topic 605, the Company identified the deliverables at the inception of the CSL License Agreement. The deliverables were determined to include (i) the M230 research, development, manufacturing and commercialization license, (ii) the research license for other Fc multimer proteins and (iii) the Company's responsibility to transfer the technology package relating to M230 to CSL. The best estimate of the selling price associated with the Company's participation on the joint steering committee was deemed to be de minimis, and therefore was not evaluated further. The Company determined that the M230 research, development, manufacturing and commercialization license does not have stand-alone value separate and apart from the Company's responsibility to transfer the M230 technology package to CSL because (1) there are no other vendors selling similar licenses on a stand-alone basis, (2) CSL does not have the contractual right to resell the license or the transferred technology, and (3) CSL is unable to use the license for its intended purpose without the technology transfer. In addition, the Company determined that the research license does not have stand-alone value. As such, the Company determined that there is one unit of accounting. The total arrangement consideration of $50 million was allocated to the single unit of accounting and will be recognized as revenue once the technology transfer is completed, which is the final item to be delivered in the unit of accounting. The technology transfer is expected to be completed by the end of 2017 . As of March 31, 2017 , $50 million was included in deferred revenue under the CSL License Agreement and was classified as a current liability in the consolidated balance sheet.

6. Share-Based Payments

Equity Award Retirement Policy

In December 2016, the Company's board of directors adopted the Momenta Pharmaceuticals, Inc. Equity Award Retirement Policy, or the Retirement Policy, to provide for the treatment of time-based options and restricted stock units upon a participant's qualifying retirement from the Company, allowing employees until January 11, 2017 to opt-out of a modification to certain of their outstanding grants of incentive stock options. Under the Retirement Policy, following the qualifying retirement of any employee of the Company or non-employee member of the board of directors, the participant's then-outstanding time-based options and restricted stock units will continue to vest during the one year period following the retirement date. In addition, the participant will have until the first anniversary of the retirement date (or 90 days following the date an option becomes first exercisable if such date is within the 90 days preceding the first anniversary of the retirement date) to exercise any vested options, except that no option may be exercised following the date upon which it would have expired under the applicable option award agreement if the participant had remained in service with the Company.

For those employees who did not opt out, the Retirement Policy amended the terms of existing grants of time-based options effective January 11, 2017; therefore, in the consolidated statement of operations for the three months ended March 31, 2017 , the Company recorded incremental compensation expense of $0.4 million related to the modification of those options, of which $0.3 million was included in the general administrative expense and $0.1 million was included in research and development expense.

Share-Based Compensation

The table below presents share-based compensation expense for research and development as well as general and administrative expense, both of which are included in operating expenses, in the three months ended March 31, 2017 and 2016 (in thousands):

	For the Three Months Ended March 31, 2017	For the Three Months Ended March 31, 2016
Research and development	$ 2,463	$ 2,065
General and administrative	4,340	2,763
Total share-based compensation expense	$ 6,803	$ 4,828

The following table summarizes share-based compensation expense by award category recorded in each of the three months ended March 31, 2017 and 2016 (in thousands):

	For the Three Months Ended March 31, 2017	For the Three Months Ended March 31, 2016
Stock options	$ 2,606	$ 2,758
Restricted stock awards and units	4,077	1,958
Employee stock purchase plan	120	112
Total non-cash share-based compensation expense	$ 6,803	$ 4,828

During the three months ended March 31, 2017 , the Company granted 1,013,274 options to its employees. The average grant date fair value of options granted was calculated using the Black-Scholes-Merton option-pricing model and the weighted average assumptions are noted in the table below. The weighted average grant date fair value of option awards granted during the three months ended March 31, 2017 and 2016 was $9.49 per option and $5.81 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 March 31, 2017	For the Three Months Ended March 31, 2016	For the Three Months Ended March 31, 2017	For the Three Months Ended March 31, 2016
Expected volatility	54%	57%	57%	56%
Expected dividends	—	—	—	—
Expected life (years)	5.7	6.1	0.5	0.5
Risk-free interest rate	2.1%	1.6%	0.5%	0.4%

At March 31, 2017 , the total remaining unrecognized compensation cost related to nonvested option awards amounted to $21.3 million , which will be recognized over the weighted average remaining requisite service period of 2.8 years .

During the three months ended March 31, 2017 , the Company issued 57,007 shares of common stock to employees under the employee stock purchase plan, or ESPP, resulting in proceeds of approximately $0.5 million .

Restricted Stock and Restricted Stock Units

The Company has granted time-based restricted stock awards to its employees, officers and board members and restricted stock units and performance-based restricted stock awards to its employees and officers.

Since April 13, 2016, the Company awarded 1,668,870 shares of performance-based restricted stock to employees and officers. The vesting of the shares is subject to the Company achieving up to two of three possible performance milestones on or before April 13, 2019. Upon achieving each of the first and second milestones, 25% of the shares will vest on the later of the milestone achievement date and the first anniversary of the grant date, and an additional 25% of the shares will vest on the one

year anniversary of such achievement date, subject to a requirement that recipients remain employees through each applicable vesting date. Each quarter, the Company evaluates the probability of achieving the milestones on or before April 13, 2019, and its estimate of the implicit service period over which the fair value of the awards will be recognized and expensed. As a result of discontinuing its necuparanib program in the third quarter of 2016 , the Company determined that only two of the three performance milestones are possible to achieve prior to April 13, 2019. The Company has determined that attainment of the remaining performance conditions is probable and is expensing the fair value of the shares over the implicit service period using the accelerated attribution method. In the three months ended March 31, 2017 , the Company recognized approximately $3.0 million of stock compensation costs related to these awards.

In the three months ended March 31, 2017 , the Company awarded 473,881 shares of time-based restricted stock units to its employees and officers. The time-based restricted stock units vest as to 25% on the one year anniversary of the grant date and as to 6.25% quarterly over three years that follow the grant date. Time-based awards are generally forfeited if the employment relationship terminates with the Company prior to vesting, except as provided in the Retirement Policy.

As of March 31, 2017 , the total remaining unrecognized compensation cost related to all nonvested time-based restricted stock and restricted stock units and performance-based restricted stock awards amounted to $20.3 million , which is expected to be recognized over the weighted average remaining requisite service period of approximately 3.0 years.

The following table summarizes restricted stock and restricted stock unit activity as of March 31, 2017 and the changes during the three months ended March 31, 2017 under the Company's 2013 Incentive Award Plan, as amended and restated (in thousands, except per share amounts):

	Number of Shares or Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2017	1,992	$ 10.64
Granted	496	18.71
Vested	(119)	12.00
Forfeited	(77)	11.55
Nonvested at March 31, 2017	2,292	$ 12.29

Nonvested restricted stock awards and restricted stock units have vesting conditions as summarized below (in thousands):

Vesting Condition	Nonvested Shares or Units
Time-based	904
Performance-based and time-based	1,388
Nonvested at March 31, 2017	2,292

7. Equity Financings

In April 2015, the Company entered into an At-the-Market Equity Offering Sales Agreement, or the 2015 ATM Agreement, with Stifel, under which the Company is authorized to issue and sell shares of its common stock having aggregate sales proceeds of up to $75 million from time to time through Stifel, acting as sales agent and/or principal. The Company is required to pay Stifel a commission of 2.0% of the gross proceeds from the sale of shares of its common stock under the 2015 ATM Agreement. From April 2015 through December 2015, the Company sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement pursuant to an effective shelf registration statement on Form S-3 previously filed with the SEC (Reg. No. 333-188227) and a related prospectus supplement, and raised net proceeds of approximately $9.3 million . The shelf registration statement on Form S-3 (Reg No. 333-188227) expired in April 2016. In February 2016, the Company filed a shelf registration statement on Form S-3 (Reg No. 333-209813) with the SEC registering the offer, sale and issuance, from time to time, of common stock, preferred stock, debt securities and warrants. In the three months ended March 31, 2017 , the Company sold approximately 1.3 million shares of common stock under the 2015 ATM Agreement, raising net proceeds of $18.5 million , of which $4.1 million was collected in April 2017 and was therefore included in other current assets in the consolidated balance sheet. The Company sold approximately an additional 2.6 million shares of common stock under this facility subsequent to quarter-end through May 3, 2017 , resulting in aggregate net proceeds of $36.9 million .

8. Commitments and Contingencies

Operating Leases

The Company leases office space and equipment under various operating lease agreements. See Note 14 " *Commitments and Contingencies* " in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of the Company's operating lease agreements.

Total operating lease commitments as of March 31, 2017 are as follows (in thousands):

April 1 to December 31, 2017	$	9,253
2018		15,369
2019		14,165
2020		14,581
2021		14,935
2022 and beyond		70,004
Total future minimum lease payments	$	138,307

Legal Contingencies

The Company is involved in various litigation matters that arise from time to time in the ordinary course of business. The process of resolving matters through litigation or other means is inherently uncertain and it is possible that an unfavorable resolution of these matters will adversely affect the Company, its results of operations, financial condition and cash flows. The Company's general practice is to expense legal fees as services are rendered in connection with legal matters, and to accrue for liabilities when losses are probable and reasonably estimable. The Company evaluates, on a quarterly basis, developments in legal proceedings and other matters that could cause an increase or decrease in the amount of any accrual on its consolidated balance sheets.

GLATOPA 40 mg/mL-Related Litigation

On September 10, 2014, Teva Pharmaceuticals Industries Ltd. and related entities, or Teva, and Yeda Research and Development Co., Ltd., or Yeda, filed a suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and sought declaratory and injunctive relief prohibiting the launch of the Company's product until the last to expire of these patents. In April 2015, Teva and Yeda filed an additional suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in March 2015 and expires in 2030. In May 2015, this suit was consolidated with the initial suit that was filed in September 2014. In November 2015, Teva and Yeda filed a suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a fourth Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in October 2015 and expires in 2030. In December 2015, this suit was also consolidated with the initial suit that was filed in September 2014. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of GLATOPA 40 mg/mL until the expiration of the patents at issue. On January 30, 2017, the District Court found the four patents to be invalid due to obviousness. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017 decision to the Court of Appeals for the Federal Circuit.

On December 19, 2016, Teva and Yeda filed suit against the Company and Sandoz Inc. in the United States District Court for the District of Delaware again in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL, for alleged infringement of an Orange Book-listed patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,402,874. On April 23, 2017, the parties filed a joint stipulation and proposed order to dismiss with prejudice claims and counterclaims regarding the suit for U.S. Patent No. 9,402,874. On May 1, 2017, the District Court entered the joint stipulation, dismissing the case.

On January 31, 2017, Teva filed a suit against the Company and Sandoz Inc. in the United States District Court for the District of New Jersey alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775, which issued in October 2015 and expires in October 2035. The Company and Sandoz Inc. filed a motion to dismiss

and a motion to transfer the suit to the United States District Court for the District of Delaware. On January 31, 2017, Teva voluntarily dismissed the Company from the New Jersey suit for U.S. Patent No. 9,155,775, maintaining the suit against Sandoz Inc.

On February 2, 2017, the Company filed a complaint in the United States District Court for the District of Delaware seeking a declaration that U.S. Patent No. 9,155,775 is invalid, not infringed or not enforceable against the Company. In March 2017, Teva filed a motion to stay further proceedings in the Delaware action pending a decision on the motion to transfer the New Jersey suit for U.S. Patent No. 9,155,775 to Delaware.

Enoxaparin Sodium Injection-related Litigation

On September 21, 2011, the Company and Sandoz Inc. sued Amphastar and Actavis 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 and Actavis from selling their Enoxaparin product in the United States. In October 2011, the District Court granted the Company's motion for a preliminary injunction and entered an order enjoining Amphastar and Actavis from advertising, offering for sale or selling their Enoxaparin product in the United States until the conclusion of a trial on the merits and required the Company and Sandoz Inc. to post a security bond of $100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded 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* , which was denied. In February 2013, the Company filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court which was denied in June 2013.

In July 2013, the District Court granted a motion by Amphastar and Actavis for summary judgment. The Company filed a notice of appeal of that decision to the CAFC. In February 2014, Amphastar filed a motion to the CAFC for summary affirmance of the District Court ruling, which the CAFC denied in May 2014. On November 10, 2015, the CAFC affirmed the District Court summary judgment decision with respect to Actavis, reversed the District Court summary judgment decision with respect to Amphastar, and remanded the case against Amphastar to the District Court. On January 11, 2016, Amphastar filed a petition for rehearing by the CAFC, which was denied on February 17, 2016. On May 17, 2016, Amphastar filed a petition for writ of certiorari for review of the CAFC decision by the United States Supreme Court, which was denied on October 3, 2016. The District Court trial is scheduled to begin on July 10, 2017. In April 2017, the Company, Sandoz Inc. and Actavis, or the Settling Parties, settled and signed reciprocal releases of all claims, and filed a voluntary stipulation with the District Court, pursuant to which the Settling Parties stipulated and agreed to dismiss with prejudice all claims and counterclaims among the Settling Parties, without fees or costs to any party, and with the Settling Parties waiving any and all right of appeal. The collateral for the security bond posted in the litigation remains outstanding. In the event that the Company is not successful in further prosecution or settlement of this action against Amphastar, and Amphastar is 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. Litigation involves many risks and uncertainties, and there is no assurance that the Company or Sandoz Inc. will prevail in this patent enforcement suit.

On September 17, 2015, Amphastar filed a complaint against the Company and Sandoz Inc. in the United States District Court for the Central District of California. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz Inc. sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal and California anti-trust laws and California unfair business laws. Amphastar is seeking unspecified damages and fees. In December 2015, the Company and Sandoz Inc. filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting that the court reverse and review the District Court's grant of transfer and in May 2016, the writ requested by Amphastar was denied. On July 27, 2016, the Company's and Sandoz Inc.'s motion to dismiss was granted by the District Court, and the case was dismissed. On August 25, 2016, Amphastar filed a notice of appeal from the dismissal with the United States Court of Appeals for the First Circuit. Briefing was completed in December 2016, and oral argument was held on February 9, 2017. On March 6, 2017, the United States Court of Appeals for the First Circuit reversed the District Court’s dismissal and remanded the case to the District Court for further proceedings. On April 6, 2017, the District Court held a scheduling conference to provide dates for the remanded case, and on April 20, 2017, the Company and Sandoz Inc. filed their renewed motion to dismiss. Trial is scheduled for April 2019.

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital, or NGH, filed a class action suit against the Company and Sandoz Inc. in the

United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic Enoxaparin Sodium Injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, the Company and Sandoz Inc. sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, the Company and Sandoz filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. On March 21, 2017, the United States District Court for the Middle District of Tennessee dismissed NGH's claim for damages against the Company and Sandoz, but allowed the case to move forward, in part, for NGH's claims for injunctive and declaratory relief. In the same opinion, the United States District Court for the Middle District of Tennessee denied our motion to transfer. While the outcome of litigation is inherently uncertain, the Company believes this suit is without merit, and it intends to vigorously defend itself in this litigation.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2016.

This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many important factors, such as those set forth under "Risk Factors" in Part II., Item 1A. of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biotechnology company focused on developing generic versions of complex drugs, biosimilars and novel therapeutics for autoimmune diseases.

To date, we have devoted substantially all of our capital resource expenditures to the research and development of our products and product candidates. Although we were profitable in fiscal years 2010 and 2011, since that time we have been incurring operating losses, and we expect to incur annual operating losses over the next several years as we advance our development portfolio. As of March 31, 2017 , we had an accumulated deficit of approximately $505.9 million . We will need to generate significant revenue to return to profitability. We expect that our return to profitability, if at all, will most likely come from the commercialization of the products in our development portfolio.

Complex Generics

GLATOPA ® 20 mg/mL—Generic Once-daily COPAXONE ® (glatiramer acetate injection) 20 mg/mL

On April 16, 2015, the FDA approved the ANDA for once-daily GLATOPA (glatiramer acetate injection) 20 mg/mL, a generic equivalent of once-daily COPAXONE® 20 mg/mL. GLATOPA 20 mg/mL is the first "AP" rated, substitutable generic equivalent of once-daily COPAXONE. Sandoz commenced sales of GLATOPA 20 mg/mL on June 18, 2015. Under our collaboration agreement with Sandoz, we earn 50% of contractually-defined profits on GLATOPA 20 mg/mL sales. For the three months ended March 31, 2017 , we recorded $23.4 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL.

GLATOPA ® 40 mg/mL—Generic Three-times-weekly COPAXONE ® (glatiramer acetate injection) 40 mg/mL

An ANDA seeking approval for GLATOPA 40 mg/mL, our generic version of three-times-weekly COPAXONE 40 mg/mL, was filed in February 2014 and remains under review by the FDA. Our GLATOPA 40 mg/mL formulation contains the same drug substance as GLATOPA 20 mg/mL, which we believe should help streamline the FDA review of the ANDA. To date, we are the only ANDA applicants for the three-times-weekly COPAXONE 40 mg/mL with an FDA-approved active pharmaceutical ingredient. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. Although the FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States, the FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL,

until satisfactory resolution of the compliance observations in the FDA warning letter. We are working with Sandoz to resolve this matter. We believe it continues to be possible for the GLATOPA 40 mg/mL ANDA to be approved in 2017.

On January 30, 2017, the District Court for the District of Delaware found invalid four Orange Book-listed patents related to COPAXONE 40 mg/mL that we were alleged to have infringed. Three of these patents had previously been found invalid in August 2016 by the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office, or PTAB, in an Inter Partes Review, or IPR, filed by an unrelated third party. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017 decision to the Court of Appeals for the Federal Circuit. This and other legal proceedings related to GLATOPA 40 mg/mL are described under *"Part II., Item 1. Legal Proceedings - GLATOPA 40 mg/mL-Related Proceedings."*

Enoxaparin Sodium Injection—Generic LOVENOX ®

Under our amended collaboration agreement with Sandoz, Sandoz is obligated to pay us 50% of contractually-defined profits on sales of Enoxaparin Sodium Injection.

Due to increased generic competition and resulting decreased market pricing for generic enoxaparin sodium injection products, Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the three months ended March 31, 2017 , and therefore we recorded no product revenue for Enoxaparin Sodium Injection in the same period.

Biosimilars

M923—Biosimilar HUMIRA ® (adalimumab) Candidate

In November 2016, following an interim analysis, we announced that the confirmatory, randomized, double-blind, multi-center, global study evaluating the efficacy, safety and immunogenicity of M923 in adult patients with moderate-to-severe chronic plaque psoriasis met its primary endpoint. Patients received up to 48 weeks treatment with M923, HUMIRA, or HUMIRA alternating with M923. The proportion of subjects who achieved the primary endpoint, at least 75% reduction in the Psoriasis Area and Severity Index, or PASI-75, following 16 weeks of treatment, was equivalent between M923 and HUMIRA. The estimated difference in responders was well within the pre-specified confidence interval, confirming equivalence. Equivalence was also achieved for all secondary efficacy endpoints, including the achievement of PASI-50, PASI-90, proportion achieving clear or near-clear skin, and change from baseline in absolute PASI score. Adverse events were comparable in terms of type, frequency, and severity, and were consistent with the published safety data for HUMIRA. Due to unexpectedly high enrollment rates, additional patients to those included in the interim analysis were enrolled in the study. These patients will be included in the final submission.

The first regulatory submission for marketing approval for M923 is planned for mid- 2017 and, subject to marketing approval and patent considerations, we are planning for the first commercial launch to be as early as the 2020 timeframe.

M923 was previously developed in collaboration with Baxalta. In June 2016, Baxalta became a wholly-owned subsidiary of Shire plc. In September 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience our collaboration agreement. On December 31, 2016 , we and Baxalta entered into an asset return and termination agreement, or the Baxalta Termination Agreement, amending certain termination provisions of the Baxalta Collaboration Agreement and making the termination of the Baxalta Collaboration Agreement effective December 31, 2016 . Baxalta was relieved of its obligations to continue to perform activities for M923 after December 31, 2016 , except for certain clinical and regulatory activities, the majority of which were completed in April 2017. In January 2017, Baxalta paid us a one-time cash payment of $51.2 million , representing the costs Baxalta would have incurred in performing the activities it would have performed under the Baxalta Collaboration Agreement through the original termination effective date.

We continue to identify and evaluate potential collaboration opportunities to further develop and commercialize M923.

M834—Biosimilar ORENCIA ® (abatacept) Candidate

On January 8, 2016, we entered into a collaboration agreement, which became effective on February 9, 2016, with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., or Mylan, to develop and commercialize M834. In November 2016, we initiated a randomized, double-blind, three-arm, parallel group, single-dose Phase 1 clinical trial in normal healthy volunteers to compare the pharmacokinetics, safety and immunogenicity of M834 to US-sourced and EU-sourced ORENCIA. We plan to report top-line data from the trial in the second half of 2017 .

We believe there is currently limited biosimilar competition for M834. Subject to development, marketing approval and patent considerations, we expect to be able to launch M834 in the 2020 timeframe to be able to be among the first biosimilars of ORENCIA on the market.

ORENCIA's composition of matter patents expire in the United States in 2019. In December 2016, the PTAB in an IPR we filed upheld the validity of Bristol-Myers Squibb's formulation patent U.S. Patent No. 8,476,239 on ORENCIA. This proceeding is further discussed below under " *Part II., Item 1. Legal Proceedings -- M834-Related Proceedings* ."

Other Biosimilar Candidates

Under our Mylan collaboration, we and Mylan are also developing five other biosimilar candidates from our portfolio in addition to M834, including our undisclosed biosimilar candidate, M710. We and Mylan will share equally costs and profits (losses) related to these earlier stage product candidates. We and Mylan are planning to initiate a clinical trial for M710 in late 2017 or early 2018. We and Mylan will share development and manufacturing responsibilities across product candidates, and Mylan will lead commercialization of the products.

Novel Therapeutics

We believe our novel programs discussed below could have the potential to produce product candidates capable of treating a large number of immunological disorders driven by antibodies, immune complexes, and Fc receptor biology. Such disorders include rheumatoid arthritis, autoimmune neurologic diseases such as Guillain-Barre syndrome, chronic inflammatory demyelinating neuropathy and myasthenia gravis, autoimmune blood disorders such as immune thrombocytopenic purpura, systemic autoimmune diseases such as dermatomyositis, lupus nephritis, and catastrophic antiphospholipid syndrome, antibody-mediated transplant rejection, and autoimmune blistering diseases, several of which have few treatment options.

M281 - Anti-FcRn Candidate

M281 is a fully-human monoclonal antibody that blocks the neonatal Fc receptor, or FcRn. A Phase 1 study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of M281 was initiated in June 2016. In January 2017, we announced that we had successfully completed the Phase 1 single ascending dose, or SAD, study in healthy volunteers. In the SAD portion of the study, M281 was well-tolerated with no serious adverse events observed. The multiple ascending portion of the Phase I study was initiated in January 2017. We plan to report the full data from the single and multiple ascending dose portions of the study in the second half of 2017 .

M230 - Selective Immunomodulator of Fc receptors (SIF3) Candidate

M230, a selective immunomodulator of Fc receptors, or SIF3, is a novel homogenous recombinant Fc multimer containing three IgG Fc regions joined carefully to maximize activity. Nonclinical data have shown that M230 enhances the molecules' avidity and affinity for the Fc receptors matching the potency and efficacy of IVIg at significantly lower doses.

Pursuant to the License and Option Agreement with CSL, effective February 17, 2017, we have granted CSL an exclusive worldwide license to research, develop, manufacture and commercialize M230. CSL plans to advance this candidate with a goal of beginning clinical development in 2017 .

M254 - hsIVIg Candidate

M254 is a hyper-sialylated version of IVIg, a therapeutic drug product that contains pooled, human immunoglobulin G, or IgG, antibodies purified from blood plasma. IVIg is used to treat several inflammatory diseases, including idiopathic thrombocytopenic purpura, Kawasaki disease, and chronic inflammatory demyelinating polyneuropathy. Our hsIVIg product is currently in nonclinical development and has the potential to be developed as a high-potency alternative to IVIg. We plan to initiate an IND-enabling toxicology study in 2017 and are targeting initiating a clinical trial in 2018. We continue to identify and explore potential collaboration opportunities to further develop and commercialize this product candidate.

Results of Operations

Comparison of Three Months Ended March 31, 2017 and 2016

Collaboration Revenue

Collaboration revenue includes both product revenue and research and development revenue earned under our collaborative arrangements. Product revenue includes our contractually-defined profits earned on Sandoz' sales of GLATOPA 20 mg/mL.

GLATOPA ® 20 mg/mL—Generic Once-daily COPAXONE ® (glatiramer acetate injection) 20 mg/mL

Sandoz commenced sales of GLATOPA 20 mg/mL in the United States on June 18, 2015. We earn 50% of contractually-defined profits on Sandoz' sales of GLATOPA 20 mg/mL. A portion of certain legal expenses for GLATOPA, including any patent infringement damages, is deducted from our profits in proportion to our 50% profit sharing interest.

For the three months ended March 31, 2017 , we recorded $23.4 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL, reflecting $23.7 million in profit share net of a deduction of $0.3 million for reimbursement to Sandoz of 50% of GLATOPA-related legal expenses incurred by Sandoz. For the three months ended March 31, 2016 , we recorded $14.8 million in product revenues from Sandoz' sales of GLATOPA 20 mg/mL. The increase in product revenues of $ 8.6 million , or 58% , from the three months ended March 31, 2016 to the three months ended March 31, 2017 was primarily due to a higher number of GLATOPA 20 mg/mL units sold. We estimate that the number of prescriptions for GLATOPA 20 mg/mL represents approximately 42% of the once-daily 20 mg/mL U.S. glatiramer acetate market.

Although the market potential of GLATOPA 20 mg/mL is negatively impacted by the conversion of patients from once-daily COPAXONE to three-times-weekly COPAXONE, which accounts for approximately 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/mL) based on volume prescribed, we believe there remains a meaningful market opportunity for GLATOPA 20 mg/mL. The price for once-daily COPAXONE 20 mg/mL has increased over 190% since 2009, and there is no other generic for relapsing forms of multiple sclerosis currently available in the United States.

Research and Development Revenue

Research and development revenue generally consists of amounts earned by us under our collaborations for:

- Technical development, regulatory and commercial milestones under the Sandoz collaboration and, where applicable, our former collaboration with Baxalta;
- Reimbursement of research and development services and reimbursement of development costs under our Sandoz collaboration and, where applicable, our former collaboration with Baxalta; and
- Recognition of upfront arrangement consideration under our Mylan collaboration and, where applicable, our former collaboration with Baxalta.

Research and development revenue was $3.2 million and $5.1 million for the three months ended March 31, 2017 and 2016 , respectively. The decrease in research and development revenue of $1.9 million, or 37% , from the three months ended March 31, 2016 to the three months ended March 31, 2017 was primarily due to the termination of the Baxalta Collaboration Agreement, effective December 31, 2016, under which we were previously reimbursed for M923 FTE and external costs and for which we recognized a portion of Baxalta's initial upfront payment in the three months ended March 31, 2016 , which were non-recurring in the same period in 2017 .

We expect collaborative research and development revenue earned by us related to FTE and external expense reimbursement from Sandoz for GLATOPA and Enoxaparin Sodium Injection will fluctuate from quarter to quarter in 2017 depending on our research and development activities. We expect to recognize the upfront payment from Mylan ratably as revenue over the respective performance period for the units of accounting with quarterly revenue in 2017 of approximately $1.8 million. Finally, we expect to recognize the $50 million upfront payment from CSL as revenue in the second half of 2017 .

Research and Development Expense

Research and development expenses consist of costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred. We track the external research and development costs incurred for each of our product candidates. Our external research and development expenses consist primarily of:

- expenses incurred under agreements with consultants, third-party contract research organizations, or CROs, and investigative sites where all of our nonclinical studies and clinical trials are conducted;

- costs of acquiring reference comparator materials and manufacturing nonclinical study and clinical trial supplies and other materials from contract manufacturing organizations, or CMOs, and related costs associated with release and stability testing; and

- costs associated with process development activities.

Internal research and development costs are associated with activities performed by our research and development organization and are not tracked on a project-by-project basis. Internal costs consist primarily of:

- personnel-related expenses, which include salaries, benefits and share-based compensation; and

- facilities and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization of leasehold improvements and equipment and laboratory and other supplies.

We have a collaboration agreement with Mylan pursuant to which we share research and development expenses related to the biosimilar candidates under the collaboration. We record expenses incurred under this collaboration arrangement for such work as research and development expense, based on the nature of the cost reimbursement. Because the collaboration arrangement is a cost sharing arrangement, we concluded that when there is a period during the collaboration arrangement during which we are owed payment from Mylan, we record the reimbursement by Mylan for its share of the development effort as a reduction of research and development expense. Amounts owed to Mylan are recorded as incremental research and development expense.

Research and development expense for the three months ended March 31, 2017 was $36.1 million , compared with $28.8 million for the three months ended March 31, 2016 . The increase of $7.3 million , or 25%, from the three months ended March 31, 2016 to the three months ended March 31, 2017 was primarily due to increased spending on M923, as the program was transitioned back to us effective December 31, 2016 in connection with the termination of the Baxalta Collaboration Agreement.

The lengthy process of securing FDA approval for generics, biosimilars and 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.

The following table sets forth, in thousands, the primary components of our research and development external expenditures, including the amortization of our intangible asset, for each of our principal development programs by product area for the three months ended March 31, 2017 and 2016 . The figures in the table include project expenditures incurred by us and reimbursed by our collaborators, but exclude project expenditures incurred by our collaborators. Although we track and accumulate personnel effort by percentage of time spent on our programs, a significant portion of our internal research and development costs, including salaries and benefits, share-based compensation, facilities, depreciation and laboratory supplies are not directly charged to programs. Therefore, our methods for accounting for internal research and development costs preclude us from reporting these costs on a project-by-project basis.

	Phase of Development as of March 31, 2017	Three Months Ended March 31,		Project Inception to March 31, 2017
		2017	2016	
External Costs Incurred by Product Area:				
Complex Generics(1)	ANDAs filed(2)	$ 1,791	$ 293	$ 106,245
Biosimilars	Various(3)	8,793	4,450	122,513
Novel Therapeutics	Various(4)	5,445	5,655	98,710
Internal Costs		20,072	18,359	
Total Research and Development Expenses		$ 36,101	$ 28,757	

(1) Includes external costs for GLATOPA and Enoxaparin Sodium Injection.

(2) On April 16, 2015, the FDA approved the ANDA for once-daily GLATOPA 20 mg/mL. Sandoz launched GLATOPA 20 mg/mL on June 18, 2015. The ANDA for GLATOPA 40 mg/mL is under FDA review. For more information, see " *—Overview—Complex Generics—GLATOPA ® 40 mg/mL—Generic Three-times-weekly COPAXONE ® (glatiramer acetate injection) 40 mg/mL.* "

(2) Biosimilars include M923, a biosimilar candidate of HUMIRA ® (adalimumab), M834, a biosimilar candidate of ORENCIA ® (abatacept), as well as five other biosimilar candidates, including our undisclosed biosimilar candidate, M710. In April 2016, enrollment in the pivotal clinical trial for M923 was completed and in November 2016, following an interim analysis, we announced top-line Phase III results including that M923 met its primary endpoint in the study. We initiated a Phase 1 clinical trial of M834 in November 2016. Our other biosimilar candidates are in discovery and process development. As a result of the cost-sharing provisions of the Mylan Collaboration Agreement, we offset approximately $5.5 million and $3.7 million against research and development costs during the three months ended March 31, 2017 and 2016 , respectively.

(3) Our novel therapeutic programs include M281, for which the multiple ascending dose portion of a Phase 1 study was initiated in January 2017; M230, which our licensee, CSL, plans to advance with a goal of beginning clinical development in 2017; M254, which is currently in preclinical development and for which we are planning to initiate an IND-enabling toxicology study in 2017; costs related to our discontinued necuparanib program; as well as other discovery and nonclinical stage programs.

External expenditures for complex generics increased by $1.5 million , or 511% from the three months ended March 31, 2016 to the three months ended March 31, 2017 as we continue to support our complex generics. External expenditures for our biosimilars programs increased by $4.3 million , or 98% , from the three months ended March 31, 2016 to the three months ended March 31, 2017 driven by our assuming responsibility for development and commercialization of M923 effective December 31, 2016. External costs of our novel therapeutic programs decreased by $0.2 million , or 4% , from the three months ended March 31, 2016 to the three months ended March 31, 2017 , driven by a decrease in costs related to our discontinued necuparanib program, partially offset by increased spend on the M281 Phase I clinical trial as well as nonclinical and manufacturing costs to advance M230 towards the clinic. Finally, internal costs grew by $1.7 million , or 9% , from the three months ended March 31, 2016 to the three months ended March 31, 2017 primarily due to increased personnel-related expenses including share-based compensation expense.

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.

General and Administrative Expense

General and administrative expenses consist primarily of salaries and other related costs for personnel in general and administrative functions, professional fees for legal and accounting services, royalty and license fees, insurance costs, and rent, facility and lab supplies, and depreciation expense.

We have a collaboration agreement with Mylan pursuant to which we share research and development expenses related to biosimilar candidates under the collaboration. We record expenses incurred under this collaboration arrangement for such work as general and administrative expense, based on the nature of the cost reimbursement. Because the collaboration arrangement is a cost sharing arrangement, we concluded that when there is a period during the collaboration arrangement during which we are owed payment from Mylan,we record the reimbursement by Mylan for its share of the development effort as a reduction of general and administrative expense. Amounts owed to Mylan are recorded as incremental general and administrative expense.

General and administrative expense for the three months ended March 31, 2017 was $23.1 million , compared with $15.6 million for the three months ended March 31, 2016 . The increase of $7.5 million , or 48% , from the three months ended March 31, 2016 to the three months ended March 31, 2017 was primarily driven by increases of $5.0 million relating to our ongoing litigation and $2.0 million in personnel-related expenses, of which $1.6 million represents share-based compensation expense associated with grants of performance-based restricted stock awards and restricted stock units.

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.

Other Income

Other income primarily includes interest income. Interest income was $0.8 million and $0.5 million for the three months ended March 31, 2017 and 2016 , respectively. The increase of $0.3 million , or 60%, from the three months ended March 31, 2016 to the three months ended March 31, 2017 was caused by higher returns on our cash balances.

Equity Financings

In April 2015, we entered into an At-the-Market Equity Offering Sales Agreement, or the 2015 ATM Agreement, with Stifel, under which we are authorized to issue and sell shares of our common stock having aggregate sales proceeds of up to $75 million from time to time through Stifel, acting as sales agent and/or principal. We are required to pay Stifel a commission of 2.0% of the gross proceeds from the sale of shares of our common stock under the 2015 ATM Agreement. From April 2015 through December 2015, we sold approximately 0.5 million shares of common stock under the 2015 ATM Agreement pursuant to an effective shelf registration statement previously filed with the SEC (Reg. No. 333-188227) and a related prospectus supplement, raising net proceeds of approximately $9.3 million . In the three months ended March 31, 2017 , the Company sold approximately 1.3 million shares of common stock under the 2015 ATM Agreement pursuant to an effective shelf registration statement previously filed with the SEC (Reg. No. 333-209813) and a related prospectus supplement, raising net proceeds of $18.5 million , of which $4.1 million was received in April 2017.

Liquidity and Capital Resources

At March 31, 2017 , we had $433.7 million in cash, cash equivalents and marketable securities and $26.5 million in collaboration receivables, which includes $23.4 million in profit share from Sandoz' sales of GLATOPA 20 mg/mL. In addition, we also held $21.8 million in restricted cash, of which $17.5 million serves as collateral for a security bond posted in the litigation against Amphastar. Our funds at March 31, 2017 were primarily invested in commercial paper, overnight repurchase agreements, asset-backed securities, corporate debt securities and United States money market funds, directly or through managed funds, with remaining maturities of 12 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 market risk at March 31, 2017 .

We have funded our operations primarily through the sale of equity securities and payments received under our collaboration and license agreements, including product revenue from Sandoz’ sales of Enoxaparin Sodium Injection and GLATOPA 20 mg/mL. Since our inception through March 31, 2017 , we have received cash of $638 million through private and public issuances of equity securities, including approximately $148 million in net proceeds from our May 2015 public offering of common stock and approximately $97 million under our At-the-Market Equity Offering Sales Agreements, or the ATM Agreements, with Stifel entered into in May 2014 and April 2015, respectively. As of March 31, 2017 , we had received a cumulative total of $754 million under our collaborations with Sandoz, including $469 million in revenues for Enoxaparin Sodium Injection and regulatory and commercial milestones related to that product, and $161 million in revenues on sales of GLATOPA 20 mg/mL and regulatory and commercial milestones related to that product. In addition, through March 31, 2017, we received $139 million under our former collaboration with Baxalta. In 2016, we received a $45 million upfront payment from Mylan, and in March 2017, we received a $50 million upfront payment from CSL under the CSL License and Option Agreement. In 2016, we received $60 million in milestone payments from Mylan, of which $27.2 million will be applied toward the funding of Mylan's 50% share of collaboration expenses that are expected to be incurred in future quarterly periods.

We are eligible to receive up to $140 million in additional contingent milestone payments from Mylan under the Mylan Collaboration Agreement, of which we expect to receive $35 million in 2017.

We expect to fund our planned operating and expenditure requirements through a combination of current cash, cash equivalents and marketable securities; equity financings, including sales of common stock under our 2015 ATM Agreement; and milestone payments and product revenues under existing collaboration agreements. We may also seek funding from new collaborations and strategic alliances, debt financings and other financial arrangements. Future funding transactions may or may not be similar to our prior funding transactions. There can be no assurance that future funding transactions will be available on favorable terms, or at all. We currently believe that our current capital resources and projected milestone payments and product revenues will be sufficient to meet our operating requirements through at least the end of 2018.

In February 2016, we filed a shelf registration statement on Form S-3 (Reg No. 333-209813) with the SEC registering the offer, sale and issuance, from time to time, of common stock, preferred stock, debt securities and warrants. Our prior shelf registration statement on Form S-3 (Reg No. 333-188227) expired in April 2016.

	Three Months Ended March 31,	
	2017	2016
	(in thousands)	
Net cash provided by operating activities	$ 63,044	$ 13,923
Net cash provided by investing activities	$ 27,348	$ 13,489
Net cash provided by financing activities	$ 19,357	$ 558
Net increase in cash and cash equivalents	$ 109,749	$ 27,970

Cash provided by operating activities

The cash provided by operating activities generally approximates our net loss adjusted for non-cash items and changes in operating assets and liabilities.

Cash provided by operating activities was $63.0 million for the three months ended March 31, 2017 reflecting a net loss of $31.8 million , which was partially offset by non-cash charges of $1.6 million for depreciation and amortization of property, equipment and intangible assets and $6.8 million in shared-based compensation. The net change in our operating assets and liabilities provided cash of $86.4 million and primarily resulted from the receipt of $50 million from CSL under the CSL License Agreement, which is included in deferred revenue, and a one-time cash payment of $51.2 million in connection with the termination of the Baxalta Collaboration Agreement, which is included in collaboration receivable, partially offset by the change in profit share receivable from Sandoz' sales of GLATOPA 20 mg/mL of $7.6 million, which is included in collaboration receivable.

Cash provided by operating activities was $13.9 million for the three months ended March 31, 2016, reflecting a net loss of $24 million, which was partially offset by non-cash charges of $2.2 million for depreciation and amortization of property, equipment and intangible assets, $4.8 million in shared-based compensation and $0.3 million for amortization of purchased premiums on our marketable securities. The net change in our operating assets and liabilities provided cash of $30.7 million and primarily resulted from the receipt of $45 million from Mylan under the Mylan Collaboration Agreement, partially offset by the change in accrued expenses of $8.3 million primarily due to the timing of costs for process development services for our biosimilars and novel therapeutics programs.

Cash provided by investing activities

Cash provided by investing activities of $27.3 million for the three months ended March 31, 2017 includes cash inflows of $76.4 million from maturities of marketable securities partially offset by cash outflows of $47.4 million for purchases of marketable securities and $1.7 million for capital equipment and leasehold improvements.

Cash provided by investing activities of $13.5 million for the three months ended March 31, 2016 includes cash outflows of $119.4 million for purchases of marketable securities and $1.5 million for capital equipment and leasehold improvements partially offset by cash inflows of $134.4 million from maturities of marketable securities.

Cash provided by financing activities

Cash provided by financing activities of $19.4 million for the three months ended March 31, 2017 includes $14.4 million of net proceeds from shares sold under the 2015 ATM Agreement and $4.9 million in proceeds from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

Cash provided by financing activities of $0.6 million for the three months ended March 31, 2016 consisted solely of net proceeds from stock option exercises and purchases of shares of our common stock through our employee stock purchase plan.

Contractual Obligations

Our major outstanding contractual obligations relate to license maintenance obligations including royalties payable to third parties as well as operating lease obligations. The disclosures relating to our contractual obligations in our Annual Report

on Form 10-K for the year ended December 31, 2016 , filed with the Securities and Exchange Commission on February 24, 2017, have not materially changed since we filed that report.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or GAAP. The preparation of these consolidated financial statements requires us 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 consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Please refer to the significant accounting policies described in 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, 2016 filed with the SEC on February 24, 2017.

Please refer to Revenue Recognition within Note 2 " *Summary of Significant Accounting Policies* " to the accompanying condensed consolidated financial statements for our discussion of our revenue recognition policy for our multiple element arrangements. The notes to our condensed consolidated financial statements are contained in Part I, Item I of this Quarterly Report on Form 10-Q.

New Accounting Standards

Please refer to Note 2 " *Summary of Significant Accounting Policies* " to the accompanying condensed consolidated financial statements for a discussion of new accounting standards. The notes to our consolidated financial statements are contained in Part I, Item I of this Quarterly Report on Form 10-Q.

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 March 31, 2017 , 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 defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of March 31, 2017 . 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 March 31, 2017 , our disclosure controls and procedures were effective at the reasonable assurance level.

There was no change in our internal control over financial reporting during the quarter ended March 31, 2017 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

GLATOPA 40 mg/mL-Related Proceedings

On September 10, 2014, Teva and Yeda filed a suit against us and Sandoz Inc. in the United States District Court for the District of Delaware in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL. The suit initially alleged infringement related to two Orange Book-listed patents for COPAXONE 40 mg/mL, each expiring in 2030, and sought declaratory and injunctive relief prohibiting the launch of our product until the last to expire of these patents. In April 2015, Teva and Yeda filed an additional suit against us and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a third Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in March 2015 and expires in 2030. In May 2015, this suit was consolidated with the initial suit that was filed in September 2014. In November 2015, Teva and Yeda filed a suit against us and Sandoz Inc. in the United States District Court for the District of Delaware alleging infringement related to a fourth Orange Book-listed patent for COPAXONE 40 mg/mL, which issued in October 2015 and expires in 2030. In December 2015, this suit was also consolidated with the initial suit that was filed in September 2014. Teva and Yeda seek declaratory and injunctive relief prohibiting the launch of GLATOPA 40 mg/mL until the expiration of the patents at issue. On January 30, 2017, the District Court found the four patents to be invalid due to obviousness. On February 2, 2017, Teva and Yeda filed a notice of appeal of the District Court's January 30, 2017 decision to the U.S. Court of Appeals for the Federal Circuit.

On December 19, 2016, Teva and Yeda filed suit against us and Sandoz Inc. in the United States District Court for the District of Delaware again in response to the filing by Sandoz Inc. of the ANDA with a Paragraph IV certification for GLATOPA 40 mg/mL, for alleged infringement of an Orange Book-listed patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,402,874. On April 23, 2017, the parties filed a joint stipulation and proposed order to dismiss with prejudice claims and counterclaims regarding the suit for U.S. Patent No. 9,402,874. On May 1, 2017, the District Court entered the joint stipulation, dismissing the case.

On January 31, 2017, Teva filed a suit against us and Sandoz Inc. in the United States District Court for the District of New Jersey alleging infringement related to an additional patent for COPAXONE 40 mg/mL, U.S. Patent No. 9,155,775, which issued in October 2015 and expires in October 2035. We and Sandoz Inc. filed a motion to dismiss and a motion to transfer the suit to the United States District Court for the District of Delaware. On January 31, 2017, Teva voluntarily dismissed us from the New Jersey suit for U.S. Patent No. 9,155,775, maintaining the suit against Sandoz Inc.

On February 2, 2017, we filed a complaint in the United States District Court for the District of Delaware seeking a declaration that U.S. Patent No. 9,155,775 is invalid, not infringed or not enforceable against us. In March 2017, Teva filed a motion to stay further proceedings in the Delaware action pending a decision on the motion to transfer the New Jersey suit for U.S. Patent No. 9,155,775 to Delaware.

M834-Related Proceedings

On July 2, 2015, we filed a petition for Inter Partes Review, or IPR, with the PTAB to challenge the validity of U.S. Patent No. 8,476,239, a patent for ORENCIA owned by Bristol-Myers Squibb, or BMS. The PTAB issued a decision instituting the IPR proceedings in January 2016, and BMS filed for a rehearing by the full PTAB. Oral arguments took place in September 2016. On December 22, 2016, the PTAB issued a decision upholding the validity of the patent. We filed a notice of appeal in the United States Court of Appeals for the Federal Court on February 22, 2017. BMS filed a motion to dismiss our appeal in the United States Court of Appeals for the Federal Court on March 29, 2017, and we filed our response on April 27, 2017.

Enoxaparin Sodium Injection-Related Proceedings

On September 21, 2011, we and Sandoz Inc. sued Amphastar and Actavis 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 and Actavis from selling their Enoxaparin product in the United States. In October 2011, the District Court granted our motion for a preliminary injunction and entered an order enjoining Amphastar and Actavis from advertising, offering for sale or selling their Enoxaparin product in the United States until the conclusion of a trial on the merits and required us and Sandoz Inc. to post a security bond of $100 million in connection with the litigation. Amphastar and Actavis appealed the decision to the Court of Appeals for the Federal Circuit, or CAFC, and in January 2012, the CAFC stayed the preliminary injunction. In August 2012, the CAFC vacated the preliminary injunction and remanded the case to the District Court. In September 2012, we filed a petition with the CAFC for rehearing by

the full court *en banc* , which was denied. In February 2013, we filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court, which was denied in June 2013.

In July 2013, the District Court granted a motion by Amphastar and Actavis for summary judgment. We filed a notice of appeal of that decision to the CAFC. In February 2014, Amphastar filed a motion to the CAFC for summary affirmance of the District Court ruling, which the CAFC denied in May 2014. On November 10, 2015, the CAFC affirmed the District Court summary judgment decision with respect to Actavis, reversed the District Court summary judgment decision with respect to Amphastar, and remanded the case against Amphastar to the District Court. On January 11, 2016, Amphastar filed a petition for rehearing by the CAFC, which was denied on February 17, 2016. On May 17, 2016, Amphastar filed a petition for a writ of certiorari for review of the CAFC decision by the United States Supreme Court, which was denied on October 3, 2016. The District Court trial is scheduled to begin on July 10, 2017. In April 2017, we, Sandoz Inc. and Actavis, or the Settling Parties, settled and signed reciprocal releases of all claims, and filed a voluntary stipulation with the District Court, pursuant to which the Settling Parties stipulated and agreed to dismiss with prejudice all claims and counterclaims among the Settling Parties, without fees or costs to any party, and with the Settling Parties waiving any and all right of appeal. In the event that we are not successful in further prosecution or settlement of this action against Amphastar, and Amphastar is able to prove it suffered damages as a result of the preliminary injunction, we could be liable for damages for up to $35 million of the security bond. Litigation involves many risks and uncertainties, and there is no assurance that we or Sandoz Inc. will prevail in this patent enforcement suit.

On September 17, 2015, Amphastar filed a complaint against us and Sandoz Inc. in the United States District Court for the Central District of California. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz Inc. sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal and California anti-trust laws and California unfair business laws. Amphastar is seeking unspecified damages and fees. In December 2015, we and Sandoz Inc. filed a motion to dismiss and a motion to transfer the case. In January 2016, the case was transferred to the United States District Court for the District of Massachusetts. In February 2016, Amphastar filed a writ of mandamus with the United States Court of Appeals for the Ninth Circuit requesting that the court reverse and review the District Court's grant of transfer, and in May 2016, the writ requested by Amphastar was denied. On July 27, 2016, our and Sandoz Inc.'s motion to dismiss was granted by the District Court, and the case was dismissed. On August 25, 2016, Amphastar filed a notice of appeal from the dismissal with the United States Court of Appeals for the First Circuit. Briefing was completed in December 2016, and oral argument was held on February 9, 2017. On March 6, 2017, the United States Court of Appeals for the First Circuit reversed the District Court's dismissal and remanded the case to the District Court for further proceedings. On April 6, 2017, the District Court held a scheduling conference to provide dates for the remanded case, and on April 20, 2017, we and Sandoz Inc. filed our renewed motion to dismiss. Trial is scheduled for April 2019.

On October 14, 2015, The Hospital Authority of Metropolitan Government of Nashville and Davidson County, Tennessee, d/b/a Nashville General Hospital, or NGH, filed a class action suit against us and Sandoz Inc. in the United States District Court for the Middle District of Tennessee on behalf of certain purchasers of LOVENOX or generic Enoxaparin Sodium Injection. The complaint alleges that, in connection with filing the September 2011 patent infringement suit against Amphastar and Actavis, we and Sandoz Inc. sought to prevent Amphastar from selling generic Enoxaparin Sodium Injection and thereby exclude competition for generic Enoxaparin Sodium Injection in violation of federal anti-trust laws. NGH is seeking injunctive relief, disgorgement of profits and unspecified damages and fees. In December 2015, we and Sandoz Inc. filed a motion to dismiss and a motion to transfer the case to the United States District Court for the District of Massachusetts. On March 21, 2017, the United States District Court for the Middle District of Tennessee dismissed NGH's claim for damages against us and Sandoz, but allowed the case to move forward, in part, for NGH's claims for injunctive and declaratory relief. In the same opinion, the United States District Court for the Middle District of Tennessee denied our motion to transfer. While the outcome of litigation is inherently uncertain, we believe this suit is without merit, and we intend to vigorously defend ourselves in this litigation.

Item 1A. RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks, uncertainties and other important factors described below in addition to other information included or incorporated by reference in this Quarterly Report on Form 10-Q before purchasing our securities. The risks, uncertainties and other important factors described below are not the only ones we face. Additional risks, uncertainties and other important factors of which we are unaware, or that we currently believe are not material, may also affect us. If any of the following risks actually occurs, our business, financial condition or results of operations would likely suffer.

Risks Relating to Our Business

If we or our collaborative partners encounter difficulties in our supply or manufacturing arrangements, including an inability by third party manufacturers to satisfy FDA quality standards and related regulatory requirements, 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, including sole source suppliers, 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. 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 scale-up 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 products 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. For example, on February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States; however, the FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter. If the FDA delays an approval of the GLATOPA 40 mg/mL until satisfactory resolution of the compliance observations in the FDA warning letter, the greater the risk to us and Sandoz of prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL. Any prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL could have a material adverse impact on our business, financial position and results of operations and could cause the market value of our common stock to decline.

In addition, any change in manufacturers, including for GLATOPA, could be costly because the commercial terms of any new arrangement could be less favorable, and the expenses and development and commercial delays relating to the transfer of necessary technology and processes could be significant. For GLATOPA 40 mg/mL, the longer the period of time that it would take for Sandoz to transfer the necessary technology and processes to a new fill/finish manufacturer, the greater the risk to us and Sandoz of prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL. Any prior or contemporaneous competition from other generic versions of COPAXONE 40 mg/mL could have a material adverse impact on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Moreover, in order to generate revenue from the sales of Enoxaparin Sodium Injection, GLATOPA 20 mg/mL, and if approved, GLATOPA 40 mg/mL, sufficient quantities of such product must also be produced in order to satisfy demand. If these contract manufacturers and suppliers, which include sole source suppliers, are unable to manufacture sufficient quantities of product or breach or terminate their manufacturing arrangements with us or Sandoz, as applicable, the development and commercialization of the affected products or product candidates could be delayed, which could have a material adverse effect on our business.

We have relied upon third parties, including sole source suppliers, to produce material for nonclinical 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 product candidates or market them.

If GLATOPA 40 mg/mL is launched following any FDA approval and prior to final resolution of product-related patent infringement litigation in our favor, we may incur significant damages.

Sandoz has the sole right to decide the timing and scope of the launch of GLATOPA 40 mg/mL following FDA approval. If Sandoz markets and sells GLATOPA 40 mg/mL following any FDA approval and prior to a final judicial resolution of product-related patent infringement litigation in our and Sandoz' favor, we and Sandoz may be subject to claims for patent infringement damages. Damages for infringement may in some instances exceed the amount of revenue earned by the infringing product. If Sandoz launches GLATOPA 40 mg/mL prior to final resolution of any product-related patent infringement litigation and Teva subsequently succeeds in any such litigation, we and Sandoz may be liable for significant damages. Our collaboration with Sandoz provides that our fifty (50) percent share of such damages would be payable from any

contractual profits due to us from sales of GLATOPA. Our payment of such damages could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Sandoz may delay or reduce the scope of a GLATOPA 40 mg/mL launch following any FDA approval until we and Sandoz prevail in product-related patent infringement litigation or until the relevant patents expire.

Since the damages associated with a GLATOPA 40 mg/mL launch prior to final resolution of any product-related patent infringement litigation in our and Sandoz' favor can be substantial, Sandoz may delay or reduce the scope of a GLATOPA 40 mg/mL launch following any FDA approval. A delayed launch could occur as late as final resolution of all GLATOPA 40 mg/mL-related patent infringement litigation in our and Sandoz' favor or, if we and Sandoz are unsuccessful in such litigation, the expiration of the GLATOPA 40 mg/mL-related patents. A launch that is delayed or reduced in scope could delay or reduce any future contractual profits due to us from sales of GLATOPA 40 mg/mL, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

Sandoz may be prevented from marketing and selling GLATOPA 40 mg/mL following any FDA approval if Teva is successful in obtaining injunctive relief.

A court may issue a temporary or permanent injunction pending the outcome of any GLATOPA 40 mg/mL-related patent infringement litigation or as a remedy if Teva prevails in any GLATOPA 40 mg/mL-related patent infringement litigation. An injunction would prevent us and Sandoz from manufacturing and selling GLATOPA 40 mg/mL and/or prohibit the use of previously manufactured GLATOPA 40 mg/mL for commercial sale until we and Sandoz prevail in litigation or the relevant patents expire. If Teva is successful in obtaining injunctive relief for any GLATOPA 40 mg/mL-related patents, Sandoz' ability to successfully commercialize GLATOPA 40 mg/mL would be significantly impaired, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline.

We may incur significant expenses and damages in the future in connection with allegations by Teva that we and Sandoz are infringing COPAXONE-related patents other than those at issue in the current GLATOPA 40 mg/mL-related patent infringement suits.

We and Sandoz are currently parties in patent infringement litigation in respect of all Orange Book-listed patents for COPAXONE 40 mg/mL as well as an additional COPAXONE 40 mg/mL-related patent. Teva may allege in the future that our and Sandoz' manufacturing and sale of GLATOPA infringes COPAXONE-related patents other than those at issue in the currently pending litigation, including patents that may issue in the future. We would incur significant expenses under the terms of our collaboration with Sandoz to respond to and litigate any such claims, the outcomes of which would be uncertain. Furthermore, we may be liable for significant damages from the contractual profits of GLATOPA 20 mg/mL and, if approved and launched, GLATOPA 40 mg/mL if we and Sandoz are found to have infringed any such patents, which could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline. Moreover, litigation concerning intellectual property and proprietary technologies can be protracted and expensive and can distract management and personnel from running our business.

If other generic versions of the brand name drugs, or other biosimilars of the reference products, for which we have products or product candidates, including GLATOPA 20 mg/mL, GLATOPA 40 mg/mL, M923 and M834, are approved and successfully commercialized, our business would suffer.

Pricing and market share of generic and biosimilar products may decline, often dramatically, as other generics or biosimilars of the same brand name drug or reference product, respectively, enter the market. Competing generics include brand name manufacturers' "authorized generics" of their own brand name products. Generally, earlier-to-market generics and biosimilars are better able to gain significantly greater market share than later-to-market competing generics and biosimilars, respectively. Accordingly, revenue and profits from GLATOPA 20 mg/mL and, if approved, our generic and biosimilar product candidates, may be significantly reduced based on the timing and number of competing generics and biosimilars, respectively. We expect GLATOPA 20 mg/mL and, if approved, certain of our generic and biosimilar product candidates may face intense and increasing competition from other generics and biosimilars. For example, Mylan and several other companies have submitted ANDAs to the FDA for generic versions of COPAXONE. A launch of an additional generic version of COPAXONE could significantly reduce anticipated revenue from GLATOPA 20 mg/mL and, if approved and launched, GLATOPA 40 mg/mL. The longer the period of time that it takes us and Sandoz to receive approval of the GLATOPA 40 mg/mL ANDA, the greater the risk of prior or contemporaneous competition from other generic versions of COPAXONE. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning

letter. The FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter.

In addition, the first biosimilar determined to be interchangeable with a particular reference product for any condition of use is eligible for a period of market exclusivity that delays an FDA determination that a second or subsequent biosimilar product is interchangeable with that reference product for any condition of use until the earlier of: (1) one year after the first commercial marketing of the first interchangeable product; (2) 18 months after resolution of a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product, based on a final court decision regarding all of the patents in the litigation or dismissal of the litigation with or without prejudice; (3) 42 months after approval of the first interchangeable product, if a patent infringement suit instituted under 42 U.S.C. § 262(l)(6) against the applicant that submitted the application for the first interchangeable product is still ongoing; or (4) 18 months after approval of the first interchangeable product if the applicant that submitted the application for the first interchangeable product has not been sued under 42 U.S.C. § 262(l)(6). A determination that another company's product is interchangeable with HUMIRA, ORENCIA or another of the reference products for which we have a biosimilar product candidate prior to approval of M923, M834 or our other applicable biosimilar product candidates may therefore delay any determination that our product is interchangeable with the reference product, which may materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue.

If an alternative version of a reference product, such as COPAXONE, HUMIRA or ORENCIA, is developed that has a new product profile and labeling, the alternative version of the product could significantly reduce the market share of the original reference product, and may cause a significant decline in sales or potential sales of our corresponding generic or biosimilar product.

Brand companies may develop alternative versions of a reference product as part of a life cycle extension strategy, and may obtain approval of the alternative version under a supplemental new drug application, for a drug, or biologics license application, for a biologic. The alternative version may offer patients added benefits such as a more convenient form of administration or dosing regimen. Should the brand company succeed in obtaining an approval of an alternative product, it may capture a significant share of the collective reference product market and significantly reduce the market for the original reference product and thereby the potential size of the market for our generic or biosimilar products. For example, Teva's three-times-weekly COPAXONE 40 mg/mL, which launched in early 2014, accounts for approximately 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/mL) based on volume prescribed. As a result, the market potential for GLATOPA 20 mg/mL has decreased, and may decrease further as additional patients are converted from once-daily COPAXONE to three-times-weekly COPAXONE. In addition, the alternative product may be protected by additional patent rights as well as have the benefit, in the case of drugs, of an additional three years of FDA marketing approval exclusivity, which would prohibit a generic version of the alternative product for some period of time. As a result, our business, including our financial results and our ability to fund future discovery and development programs, would suffer.

If the market for a reference product, such as COPAXONE, HUMIRA or ORENCIA, significantly declines, sales or potential sales of our corresponding generic and biosimilars product and product candidates may suffer and our business would be materially impacted.

Competition in the biotechnology industry is intense. Reference products face competition on numerous fronts as technological advances are made or new products are introduced that may offer patients a more convenient form of administration, increased efficacy or improved safety profile. As new products are approved that compete with the reference product to our generic products and product candidates and our biosimilar product candidates, respectively, sales of reference products and biosimilar and generics may be significantly and adversely impacted and may render the reference products obsolete.

Current injectable treatments commonly used to treat multiple sclerosis, including COPAXONE, are competing with novel therapeutic products, including oral therapies. These oral therapies may offer patients a more convenient form of administration than COPAXONE and may provide increased efficacy.

If the market for the reference 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.

Our future GLATOPA product revenue is dependent on the continued successful commercialization of GLATOPA 20 mg/mL and successful commercialization of GLATOPA 40 mg/mL, if approved.

Our near-term ability to generate GLATOPA product revenue depends, in large part, on Sandoz' ability to continue to manufacture and commercialize GLATOPA 20 mg/mL, and manufacture and commercialize GLATOPA 40 mg/mL, if approved. On February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA warning letter does not restrict the production or shipment of the GLATOPA 20 mg/mL product that is currently marketed by Sandoz in the United States; however, the FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter.

Our near-term ability to generate GLATOPA product revenue also depends in large part on Sandoz' ability to maintain market share and the pricing levels for GLATOPA 20 mg/mL and, if approved, GLATOPA 40 mg/mL, as Sandoz competes with Teva's three-times-weekly COPAXONE 40 mg/mL, which currently accounts for approximately 81% of the overall U.S. glatiramer acetate market (20 mg/mL and 40 mg/mL) based on volume prescribed. Because GLATOPA 20 mg/mL is only a substitutable generic version of the once-daily 20 mg/mL formulation of COPAXONE, the market potential of GLATOPA 20 mg/mL is negatively impacted by the conversion of patients from once-daily COPAXONE 20 mg/mL to three-times-weekly COPAXONE 40 mg/mL prior to the approval and launch of the GLATOPA 40 mg/mL product, which is currently pending FDA approval. Following any such approval and launch of the GLATOPA 40 mg/mL product, our near-term ability to generate GLATOPA product revenue will continue to depend on Sandoz' ability to compete with Teva's three-times-weekly COPAXONE 40 mg/mL product. In addition, other competitors may in the future receive approval to market generic versions of the 20 mg/mL or 40 mg/mL formulations of COPAXONE which would further impact our product revenue, which is based on a fifty-percent contractual profit share and, as a result, our business, including our near-term financial results and our ability to utilize GLATOPA revenue to fund future discovery and development programs, may suffer.

Any future Enoxaparin Sodium Injection product revenue is dependent on the successful manufacture and commercialization of Enoxaparin Sodium Injection .

Our near-term ability to generate Enoxaparin Sodium Injection product revenue depends, in large part, on Sandoz' ability to manufacture and commercialize Enoxaparin Sodium Injection and compete with LOVENOX brand competition as well as authorized and other generic competition. Sandoz is facing increasing competition and pricing pressure from brand, authorized generic and other currently-approved generic competitors, which has and will continue to impact Sandoz' net sales and profits from Enoxaparin Sodium Injection, and therefore our product revenue. Furthermore, other competitors may in the future receive approval to market generic Enoxaparin products which would further impact our product revenue, which is based on a fifty-percent contractual profit share. Due to these circumstances, the resulting market price for our Enoxaparin Sodium Injection product has substantially decreased and may decrease further. Sandoz did not record any profit on sales of Enoxaparin Sodium Injection in the three months ended March 31, 2017, and therefore we recorded no product revenue for Enoxaparin Sodium Injection in the same period. Accordingly, we do not anticipate significant Enoxaparin Sodium Injection revenue in the near term.

If our patent litigation against Amphastar related to Enoxaparin Sodium Injection is not successful or third parties are successful in antitrust litigation against us relating to Enoxaparin Sodium Injection, we may be liable for damages and our business may be materially harmed.

In the event that we are not successful in our continued prosecution of our suit against Amphastar and Amphastar is able to prove it suffered damages as a result of the preliminary injunction preventing it from selling its Enoxaparin product in the United States, we could be liable for up to $35 million of the security bond for such damages. Moreover, if third parties are successful in antitrust litigation against us for asserting our Enoxaparin patent rights, they may be able to recover damages incurred as a result of enforcement of our patent rights, thereby negatively affecting our financial condition and results of operations.

If efforts by manufacturers of reference products to delay or limit the use of generics or biosimilars are successful, our sales of generic and biosimilar products may suffer.

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

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

- seeking to restrict biosimilar commercialization options by making mandatory the optional right to adjudicate patent rights under Section 351(l) of the Biologics Price, Competition and Innovation Act or restricting access by biosimilar and generic applicants by litigation or legislative action to the use of inter partes patent review proceedings at the U.S. Patent Office to challenge invalid biologic patent rights;

- 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 or biosimilar applications or to influence the adoption of policy with regard to the submission of biosimilar applications;

- appealing denials of Citizen Petitions in United States federal district courts and seeking injunctive relief to reverse approval of generic drug or biosimilar applications;

- restricting access to reference products for equivalence and biosimilarity testing that interfere with timely generic and biosimilar development plans, respectively;

- conducting medical education with physicians, payers and regulators that claim that generic or biosimilar products are too complex for generic or biosimilar approval and influence potential market share;

- seeking state law restrictions on the substitution of generic and biosimilar products at the pharmacy without the intervention of a physician or through other restrictive means such as excessive recordkeeping requirements or patient and physician notification;

- seeking federal or state regulatory restrictions on the use of the same non-proprietary name as the reference brand product for a biosimilar or interchangeable biologic;

- seeking federal reimbursement policies that do not promote adoption of biosimilars and interchangeable biologics;

- seeking changes to the United States Pharmacopeia, an industry recognized compilation of drug and biologic 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 or biosimilars; and

- influencing legislatures so that they attach special regulatory exclusivity or patent extension amendments to unrelated federal legislation.

The FDA's practice is to rule within 150 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 150-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. For example, Teva Neuroscience, Inc. filed eight Citizen Petitions regarding GLATOPA 20 mg/mL, all of which have been denied, dismissed or withdrawn. Teva also sought 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 or biosimilar products. Teva may seek to file additional Citizen Petitions pertaining to the GLATOPA 40 mg/mL ANDA or file other forms of comments to the FDA, and seek to delay or prevent the FDA approval of the GLATOPA 40 mg/mL ANDA, which could materially harm our business.

If these efforts to delay or block competition are successful, we may be unable to sell our generic and biosimilar products, if approved, which could have a material adverse effect on our sales and profitability.

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, biosimilars and novel therapeutics, conducting nonclinical 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.

We face, and will continue to face, competition with regard to our products and, if approved, our product candidates, based on many different factors, including:

- the safety and effectiveness of our products;
- with regard to our generic products and our generic and biosimilar product candidates, the differential availability of clinical data and experience and willingness of physicians, payers and formularies to rely on biosimilarity data;
- 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 positions.

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 be adversely impacted.

Drug products and biologics are sold through various channels, including retail, mail order, and to hospitals through group purchasing organizations, or GPOs. The distribution of such products is also managed by pharmacy benefit management firms, or PBMs, such as Express Scripts or CVS. These GPOs and PBMs rely on competitive bidding, discounts and rebates across their purchasing arrangements. We believe that we, in collaboration with commercial collaboration partners, will need to maintain adequate drug supplies, remain price competitive, comply with FDA regulations and provide high-quality products to establish and maintain relationships with GPOs and PBMs. The GPOs, PBMs and other customers 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 products to certain market segments. Our sales could also be negatively affected by any rebates, discounts or fees that are required by, or offered to, GPOs, PBMs, and customers, including wholesalers, distributors, retail chains or mail order services, to gain and retain market acceptance for our or our competitors' products. For example, if PBMs, distributors and other customers contract with Teva for net price discounts or rebates on COPAXONE 20 mg/mL and 40 mg/mL in exchange for exclusivity or preferred status for COPAXONE prior to approval and launch of GLATOPA 40 mg/mL, our opportunity to capture market share would be significantly restricted for the term of these contracts even after a launch of GLATOPA 40 mg/mL. If we or our collaborators are unable to establish and maintain competitive 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 adversely affect our ability to generate sufficient revenue from product sales to maintain or grow our business.

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 payers. Acceptance of our products will be a function of our products being clinically useful, being cost effective and demonstrating sameness, in the case of our generic product candidate, and biosimilarity or interchangeability, in the case of our biosimilar product candidates, 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 or biosimilars;
- the absence of, or limited clinical data available from, sameness testing of our complex generic products and biosimilarity or interchangeability testing of our biosimilar 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 payer 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.

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 key person 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. Another component of retention is the intrinsic value of equity awards, including stock options. Stock options granted to our executives and employees may be under pressure given the volatility of our stock performance and at such times may not always provide a retentive effect. If we lose key members of our management team, or are unable to attract and retain qualified personnel, our business could be negatively affected.

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. We cannot be sure that the product liability insurance coverage we

maintain 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.

Our business and operations would suffer in the event of system failures or security breaches.

Our operations rely on the secure processing, storage and transmission of confidential and other information in our and our third party contractors' computer systems and networks. Our internal computer systems are vulnerable to breakdown or breach, including as a result of computer viruses, security breaches by individuals with authorized access, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The increased use of mobile and cloud technologies can heighten these and other operational risks. Moreover, systems breaches are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. Any breakdown or breach by employees or others may pose a risk that sensitive data, including clinical trial data, intellectual property, trade secrets or personal information belonging to us, our patients or our collaborators may be exposed to unauthorized persons or to the public. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture and commercialize our products and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our products and product candidates could be delayed, we could suffer reputational harm, we could be subject to regulatory action, and the trading price of our common stock could be adversely affected. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to breakdown or breach of our computer systems and other related breaches.

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

As we advance an increasing number of 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 lease additional or alternative facilities and manage additional relationships with various collaborative partners, suppliers and other organizations. The market for laboratory and office facilities is highly competitive near our current location. If we are not successful in leasing additional or alternative space in our current area and have to move our facilities, the timing of our development programs could be disrupted.

In addition, 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 can 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 incur costs and allocate resources to identify and develop additional product candidates or acquire or make investments in companies or technologies without realizing any benefit, which could have an adverse effect on our business, results of operations and financial condition or cash flows.

Along with continuing to progress our current product candidates, the long-term success of our business also depends on our ability to successfully identify, develop and commercialize additional product candidates. Research programs to identify

new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs and product candidates that ultimately prove to be unsuccessful.

In addition, 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 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.

If we fail to maintain appropriate internal controls in the future, we may not be able to report our financial results accurately, which may adversely affect our stock price and our business.

Our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' audit of that assessment requires the commitment of significant financial and managerial resources.

Internal control over financial reporting has inherent limitations, including human error, the possibility that controls could be circumvented or become inadequate because of changed conditions, and fraud. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or the Sarbanes-Oxley Act of 2002, as amended. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our stock and our business.

Risks Relating to Our Financial Position and Need for Additional Capital

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 March 31, 2017 , our accumulated deficit was $506 million . We may incur annual operating losses over the next several years as we expand our product development, commercialization and discovery efforts. In addition, we must successfully develop and obtain regulatory approval for our product candidates, and effectively manufacture, market and sell any products 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 products 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 potential profitability will also be adversely impacted by the entry of competitive products and, if so, the degree of the impact could be affected by 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 enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other therapeutic candidates or continue our operations. A decline in the value of our company could cause our shareholders to lose all or part of their investment.

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 delay, limit or cease our product development efforts or other operations. If we are unable to fund our obligations under our collaboration and license agreements, we may breach those agreements and our collaboration partners could terminate those agreements.

As of March 31, 2017 , we had cash, cash equivalents and marketable securities totaling approximately $433.7 million . For the quarter ended March 31, 2017 , we had a net loss of $31.8 million and our operations provided cash of $63.0 million . We will continue to require substantial funds to conduct research and development, process development, manufacturing, nonclinical 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 and commercialization of our product 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 will depend on many factors, including but not limited to:

- the level of sales of GLATOPA 20 mg/mL;
- the successful commercialization of GLATOPA 40 mg/mL and our other product candidates;
- the cost of advancing our product candidates and funding our development programs, including the costs of nonclinical and clinical studies and obtaining regulatory approvals;
- the receipt of continuation payments under our Mylan Collaboration Agreement;
- the receipt of milestone payments under our CSL License Agreement;
- the continuation without disruption of development and manufacturing activities of M923 following Baxalta’s termination of the Baxalta Collaboration Agreement, which was effective on December 31, 2016;
- the timing of FDA approval of the products of our competitors;
- the cost of litigation, including with Amphastar relating to Enoxaparin Sodium Injection, that is not otherwise covered by our collaboration agreements, 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 additional strategic alliances for our non-partnered programs, such as M923, as well as the terms and timing of any milestone, royalty or profit share payments thereunder;

- the continued progress in our research and development programs, including completion of our nonclinical studies and clinical trials;
- the cost of acquiring and/or in-licensing other technologies, products or assets; and
- the cost of manufacturing, marketing and sales activities, if any.

We expect to finance and manage our planned operating and capital expenditure requirements principally through our current cash, cash equivalents and marketable securities, capital raised through our collaboration and license agreements and equity financings, including utilization of our At-the-Market financing facility, continuation and milestone payments and product revenues under existing collaboration and license agreements. We believe that these funds will be sufficient to meet our operating requirements through at least the end of 2018. We may seek additional funding in the future through third-party collaborations and licensing arrangements, public or private debt financings or from other sources. Additional funds may not be available to us on acceptable terms or at all. 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 may not be able to fund our obligations under one or more of our collaboration and license agreements, which could enable one or more of our collaborators to terminate their agreements with us, and therefore harm our business, financial condition and results of operations.

Raising additional capital by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may seek to raise the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaboration and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect our stockholders' rights or, in the case of debt securities, require us to pay interest that would reduce our cash flows from operations or comply with certain covenants that could restrict our operations. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

Risks Relating to Development and Regulatory Approval

The future success of our business is significantly dependent on the success of our GLATOPA 40 mg/mL product candidate. If we are not able to obtain regulatory approval for the commercial sale of our GLATOPA 40 mg/mL product candidate, 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 GLATOPA 40 mg/mL. Our application for GLATOPA 40 mg/mL has been under review with the FDA since February 2014. To receive approval, we will be required to demonstrate to the satisfaction of the FDA, among other things, that GLATOPA 40 mg/mL:

- contains the same active ingredients as COPAXONE 40 mg/mL;
- is of the same dosage form, strength and route of administration as COPAXONE 40 mg/mL, and has the same labeling as the approved labeling for COPAXONE 40 mg/mL, with certain exceptions; and
- meets compendia 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 GLATOPA 40 mg/mL to COPAXONE 40 mg/mL will be based, in part, on our demonstration of the chemical equivalence of our version to its respective reference listed drugs. The FDA may not agree that we have adequately characterized GLATOPA 40 mg/mL or that GLATOPA 40 mg/mL and COPAXONE 40 mg/mL are chemical equivalents. In that case, the FDA may require additional information, including nonclinical or clinical trial 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 GLATOPA 40 mg/mL will receive FDA approval as therapeutically equivalent to COPAXONE 40 mg/mL.

In the event that the FDA modifies its current standards for therapeutic equivalence with respect to generic versions of COPAXONE 40 mg/mL, or requires us to conduct clinical trials or complete other lengthy procedures, the commercialization of GLATOPA 40 mg/mL could be delayed or prevented or become more expensive. Regulatory approval of this or any other product may also be significantly delayed where manufacturing inspections are pending or have unresolved pending compliance issues. Delays in any part of the process or our inability to obtain regulatory approval for GLATOPA 40 mg/mL could adversely affect our operating results by restricting or significantly delaying our introduction of GLATOPA 40 mg/mL.

Moreover, on February 17, 2017, we announced that Sandoz' third party fill/finish manufacturing partner for GLATOPA, Pfizer Inc., received an FDA warning letter. The FDA may withhold approval of pending drug applications listing the Pfizer Inc. facility, including the ANDA for GLATOPA 40 mg/mL, until satisfactory resolution of the compliance observations in the FDA warning letter.

Although the BPCI Act establishes a regulatory pathway for the approval by the FDA of biosimilars, the standards for determining biosimilarity and interchangeability for biosimilars are only just being implemented by the FDA under recently developed and developing guidance. Therefore, substantial uncertainty remains about the potential value of our scientific approach and regulatory strategy for biosimilar development.

The regulatory climate in the United States for biosimilar versions of biologic and complex protein products remains uncertain, even following the enactment of legislation establishing a regulatory pathway for the approval of biosimilars under the Biologics Price Competition and Innovation Act, or BPCI Act. For example, the FDA only recently issued a series of draft and final guidance documents on certain matters concerning approval of biosimilars, interchangeable biologics, non-proprietary naming and labeling, as well as quality and scientific considerations. Experience will develop as the number of products and applications increase. The pathway contemplates approval of two categories of follow-on biologic products: (1) biosimilar products, which are highly similar to the existing reference product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences from the reference product and (2) interchangeable biologic 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 reference product. Only interchangeable biosimilar products would be considered substitutable at the retail pharmacy level without the intervention of a physician. The 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 biosimilarity and/or interchangeability, reduces the need for large scale clinical trials or other testing, and raises the scientific quality requirements for our competitors to demonstrate that their products are highly similar to a reference 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 within the context of the biosimilar meeting and application review process. 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. Our strategy to reduce and target clinical requirements by relying on analytical and functional nonclinical data may not be successful or may take longer than strategies that rely more heavily on clinical trial data.

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

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

Furthermore, the regulatory pathway creates the risk that the reference product 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 interchangeable biosimilars. Finally, the legislation also creates the risk that, as reference product and biosimilar companies gain experience with the regulatory pathway, subsequent FDA determinations or court rulings could create additional areas for potential disputes and resulting delays in biosimilars approval.

In addition, there is reconsideration and legislative debate that could lead to the repeal or amendment of the 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. Similarly, the legislative debate at the federal level regarding the federal government budget in 2013 restricted federal agency funding for the biosimilar pathway, including biosimilar user fee funding for fiscal year 2014, and has resulted in delays in hiring and in the conduct of meetings with biosimilar applicants and the review of biosimilar meeting and application information. The scheduling and conduct of biosimilar meeting and applications review was also suspended during the U.S. Government shutdown in October 2013, and could be subject to future suspensions as a result of future deadlocks in passage of federal appropriations bills in 2017 or future years. In addition, the hiring and regulatory freeze implemented by the federal government in 2017 and other potential regulatory reform initiatives could also impact the future implementation of the biosimilar regulatory pathway. While proposals to repeal the Affordable Care Act do not appear to include proposals to repeal the BPCI Act, there is still some uncertainty about that possibility. Depending on the timing and the extent of these funding, meeting and review disruptions, our development of biosimilar products could be delayed.

Our opportunity to realize value from the potential of the biosimilars market is difficult and challenging due to the significant scientific and development expertise required to develop and consistently manufacture complex protein biologics.

The market potential of biosimilars may be difficult to realize, in large part due to the challenges of successfully developing and manufacturing biosimilars. Biologics are therapeutic proteins and are much more complex and much more difficult to characterize and replicate than small-molecule, chemically synthesized drugs. Proteins tend to be 100 to 1000 times larger than conventional drugs, and are more susceptible to physical factors such as light, heat and agitation. They also have greater structural complexity. Protein molecules differ from one another primarily in their sequence of amino acids, which results in folding of the protein into a specific three-dimensional structure that determines its activity. Although the sequence of amino acids in a protein is consistently replicated, there are a number of changes that can occur following synthesis that create inherent variability. Chief among these is the glycosylation, or the attachment of sugars at certain amino acids. Glycosylation is critical to protein structure and function, and thoroughly characterizing and matching the glycosylation profile of a targeted biologic is essential and poses significant scientific and technical challenges. Furthermore, it is often challenging to consistently manufacture proteins with complex glycosylation profiles, especially on a commercial scale. Protein-based therapeutics are inherently heterogeneous and their structure is highly dependent on the production process and conditions. Products from one production facility can differ within an acceptable range from those produced in another facility. Similarly, physicochemical differences can also exist among different lots of the same product produced at the same facility. The physicochemical complexity and size of biologics creates significant technical and scientific challenges in their replication as biosimilar products. Accordingly, the technical complexity involved and expertise and technical skill required to successfully develop and manufacture biosimilars poses significant barriers to entry. Any difficulties encountered in developing and producing, or any inability to develop and produce, biosimilars could adversely affect our business, financial condition and results of operations.

Even if we are able to obtain regulatory approval for our generic and biosimilar 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 corresponding reference product. If our generic or biosimilar products are not substitutable at the pharmacy level for the corresponding reference product, 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 reference 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 for generic drugs. As a result, in states that do not deem our generic drugs and 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 reference product. Should this occur with respect to one of our generic drugs or 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, reference product pharmaceutical companies are lobbying state legislatures and the FDA to enact physician prescription requirements, or in the absence of a prescription, physician and patient notification

requirements, special labeling requirements and unique naming requirements for biosimilars which if enacted could create barriers to substitution and adoption rates of interchangeable biologics as well as non-interchangeable biosimilars. Should this occur with respect to one of our biosimilars or interchangeable biologic product candidates in a discriminatory manner, it could materially reduce sales in those states which would substantially harm our business. To date, the FDA has adopted a non-discriminatory policy that would apply the same non-proprietary naming requirements to reference products.

If our nonclinical studies and clinical trials for our novel product candidates are not successful, we will not be able to obtain regulatory approval for commercial sale of those product candidates.

To obtain regulatory approval for the commercial sale of our novel product candidates, we are required to demonstrate through nonclinical studies and clinical trials that our product candidates are safe and effective. Nonclinical studies and clinical trials of novel product candidates are lengthy and expensive and the historical failure rate for novel product candidates is high.

A failure of one or more of our nonclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, nonclinical studies and clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our novel product 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 nonclinical studies or clinical trials may produce negative or inconclusive results, and we may be required to conduct additional nonclinical 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;
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or our product candidates may have other unexpected characteristics; and
- we may decide to modify or expand the clinical trials we are undertaking if new agents are introduced that influence current standard of care and medical practice, warranting a revision to our clinical development plan.

The results from nonclinical studies of a novel product candidate and in initial human clinical studies of a novel product candidate may not predict the results that will be obtained in subsequent human clinical trials. If we are required by regulatory authorities to conduct additional clinical trials or other testing of our novel 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 novel product 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 novel product candidates. 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 pharmaceutical products we develop will be subject to ongoing regulatory review, including the review of clinical results that 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. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs, and to spur innovation, but its ultimate implementation remains unclear. 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 payers 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 payers, both in the United States and in foreign markets. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer'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 payer 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 payer. 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 payer will reimburse the use of any product incorporating new technology. Even when a payer determines that a product is eligible for reimbursement, the payer 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 payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both CMS and other third-party payers may have sufficient market power to demand significant price reductions. Due in part to actions by third-party payers, 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.

We also anticipate that application of the existing and evolving reimbursement regimes to biosimilar products will be somewhat uncertain. In the 2016 Physician Fee Schedule Final Rule, CMS made it clear that the payment amount for a biosimilar is based on the average sales price of all products included within the same billing and payment code. In general, this means that CMS will group biosimilar products that rely on a common reference product's biologics license application into the same payment calculation, and these products will share a common payment limit and billing code. Separate codes could reduce or significantly impair the value of interchangeability of the biosimilar. However, it is unclear what effect this will have on private payers. Reimbursement uncertainty could adversely impact market acceptance of biosimilar products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payers 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 MMA changed the way Medicare covers and reimburses for pharmaceutical products. The legislation introduced a new reimbursement methodology based on average sales prices for pharmaceutical products that are used in hospital settings or under the direct supervision of a physician and, starting in 2006, expanded Medicare coverage for pharmaceutical product purchases by the elderly. In addition, the MMA requires the creation of formularies for self-administered pharmaceutical products, and provides authority for limiting the number of pharmaceutical products that will be covered in any therapeutic class and provides for plan sponsors to negotiate prices with manufacturers and suppliers of covered pharmaceutical products. As a result of the MMA and the expansion of federal coverage of pharmaceutical 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 pharmaceutical product benefits for Medicare beneficiaries, private payers 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 payers.

Furthermore, healthcare reform legislation that was enacted in 2010 and is now being implemented 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 pharmaceutical products sold into the Medicaid program, an extension of the rebate requirement to

pharmaceutical products used in risk-based Medicaid managed care plans, an extension of mandatory discounts for pharmaceutical products sold to certain critical access hospitals, cancer hospitals and other covered entities, and discounts and fees applicable to brand-name pharmaceutical products. 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.

Moreover, increasing efforts by governmental and third-party payers, in the United States and abroad, to cap or reduce healthcare costs or introduce price controls or price negotiation may cause the government or other organizations to limit both coverage and level of reimbursement for approved products and, as a result, they may not cover or provide adequate payment for our products and product candidates. We expect to experience pricing pressures in connection with the sale of any of our products and product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Additionally, the BPCI Act establishes an abbreviated regulatory pathway for the approval of biosimilars and provides that reference products may receive 12 years of market exclusivity, with a possible six-month extension for pediatric products. By creating a new approval pathway for biosimilars and adjusting reimbursement for biosimilars, the new law could promote the development and commercialization of biosimilars. However, given the uncertainty of how the law will be interpreted and implemented, the impact of the law on our strategy for biosimilars 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 biosimilars products alike depending on an applicant's clinical data, effectiveness and cost profile. If a reference 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 biosimilars based on cost savings, it could also have the effect of reducing biosimilars' market share.

The full effects of the U.S. healthcare 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. In 2017 and beyond, we may face additional uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the U.S. healthcare reform legislation. There is no assurance that the U.S. healthcare reform legislation, as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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. 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 GLATOPA 40 mg/mL 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. Until the backlog of ANDA filings is reduced, our application for GLATOPA 40 mg/mL and any supplements may be subject to significant delays during their review cycles, which may adversely affect our business and financial condition. In addition, the hiring freeze implemented by the federal government in 2017 could also impact the review and potential approval of our application for GLATOPA 40 mg/mL, which may adversely affect our business and financial condition.

Risks Relating to Intellectual Property

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, the first inventor to file a patent application is 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 U.S. PTO, or become involved in opposition, derivation, reexamination, IPR, or interference proceedings challenging our patent rights or the patent rights of others. For example, several of our European patents are being challenged in opposition proceedings before the European Patent Office. 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. PTO 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.

The breadth of patent claims allowed in any patents issued to us or to others may be unclear. 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 been alleged or 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 remain 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 continue 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 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 and Rockefeller University, which give us rights to intellectual property that may be necessary for certain parts of 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 2006 Sandoz Collaboration Agreement is important to our business. If Sandoz AG fails to adequately perform under this collaboration, or if we or Sandoz AG terminate all or a portion of this collaboration, the development and commercialization of some of our products and product candidates, including GLATOPA 20 mg/mL and GLATOPA 40 mg/mL, would be impacted, delayed or terminated and our business would be adversely affected.

Either we or Sandoz AG may terminate the 2006 Sandoz Collaboration Agreement for material uncured breaches or certain events of bankruptcy or insolvency by the other party. For some of the products, for any termination of the 2006 Sandoz Collaboration Agreement other than a termination by Sandoz AG 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 AG 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 AG terminates the 2006 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 AG 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 AG terminates due to our uncured breach or bankruptcy, Sandoz AG 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 2006 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, if we were able to do so, could cause significant delays that could prevent us from completing the development and commercialization of such product. Any alternative collaboration could also be on less favorable terms to us. Accordingly, if the 2006 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.

Under our collaboration agreement, we are dependent upon Sandoz AG to successfully continue to commercialize GLATOPA 20 mg/mL and are significantly dependent on Sandoz AG to successfully commercialize GLATOPA 40 mg/mL. We do not fully control Sandoz AG's commercialization activities or the resources it allocates to our products. While the 2006 Sandoz Collaboration Agreement contemplates joint decision making and alignment, our interests and Sandoz AG's interests may differ or conflict from time-to-time or we may disagree with Sandoz AG's level of effort or resource allocation. Sandoz AG may internally prioritize our products and product candidates differently than we do or it may fail to allocate sufficient resources to effectively or optimally commercialize our products and alignment may only be achieved through dispute resolution. If these events were to occur, our business would be adversely affected.

The development and commercialization of our lead biosimilar product candidate, M923, could be delayed or terminated as a result of the termination of the Baxalta Collaboration Agreement, and our business may be adversely affected.

On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement, or the Baxalta Termination. On December 31, 2016, we and Baxalta entered into an Asset Return and Termination Agreement pursuant to which the effective date of the Baxalta Termination was December 31, 2016. Following the effective date of the Baxalta Termination, Baxalta is not obligated to continue to perform development, manufacturing or commercialization activities for M923 except for certain transitional clinical and regulatory activities, the majority of whichwere completed in April 2017. There could be changes or delays in the timing of the M923 program in connection with the return of the M923 program to us.

In addition, following the effective date of the Baxalta Termination, we have the right to research, develop, manufacture and commercialize M923 or license a third party to do so. In the event we elect to research, develop, manufacture and commercialize M923 by ourselves, we would need to expand our internal capabilities, in connection with which there could be significant delays in the M923 program. In the event we elect to license M923 to a third party, the terms of such a license and collaboration could be less favorable than those under the Baxalta Collaboration Agreement, and finding and negotiating a new collaboration could cause significant delays in the M923 program. Any of the delays described above could prevent us from commercializing M923. In addition, we may need to seek additional financing to support the research, development and commercialization of M923, or alternatively we may decide to discontinue M923, which could have a material adverse effect on our business.

The Mylan Collaboration Agreement is important to our business. If we or Mylan fail to adequately perform under the Agreement, or if we or Mylan terminate the Mylan Collaboration Agreement, the development and commercialization of one or more of our biosimilar candidates, including M834, could be delayed or terminated and our business would be adversely affected.

The Mylan Collaboration Agreement may be terminated by either party for breach by, or bankruptcy of, the other party; for its convenience; or for certain activities involving competing products or the challenge of certain patents. Other than in the case of a termination for convenience, the terminating party shall have the right to continue the development, manufacture and commercialization of the terminated products in the terminated countries. In the case of a termination for convenience, the other party shall have the right to continue. If a termination occurs, the licenses granted to the non-continuing party for the applicable product will terminate for the terminated country. Subject to certain terms and conditions, the party that has the right to continue the development or commercialization of a given product candidate may retain royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the applicable product in the country or countries for which termination applies.

If the Mylan Collaboration Agreement were terminated and we had the right to continue the development and commercialization of one or more terminated products, to fully exercise that right, we would need to expand our internal capabilities or enter into another collaboration, which, if we were able to do so, could cause significant delays that could prevent us from commercializing those products. Any alternative collaboration could be on less favorable terms to us. In addition, we may need to seek additional financing to support the development and commercialization of any terminated products, or alternatively we may decide to discontinue one or more terminated products, which could have a material adverse effect on our business. If the Mylan Collaboration Agreement were terminated and Mylan had the right to continue the development and commercialization of one or more terminated products, we would have no influence or input into those activities.

Under the Mylan Collaboration Agreement, we are dependent upon Mylan to successfully perform its responsibilities and activities, including conducting clinical trials for certain products and leading the commercialization of products. We do not control Mylan's execution of its responsibilities, including commercialization activities, or the resources it allocates to our products. Our interests and Mylan's interests may differ or conflict from time to time, or we may disagree with Mylan's level of effort or resource allocation. Mylan may internally prioritize our products and product candidates differently than we do or it may not allocate sufficient resources to effectively or optimally execute its responsibilities or activities. If these events were to occur, our business would be adversely affected.

The CSL License Agreement is important to our business. If we or CSL fail to adequately perform under the Agreement, or if we or CSL terminate the Agreement, the development and commercialization of our novel therapeutic, M230, could be delayed or terminated and our business would be adversely affected.

CSL may terminate the CSL License Agreement on a product-by-product basis subject to notice periods and certain circumstances related to clinical development. We may terminate the CSL License Agreement under certain circumstances related to the development of M230 and if no activities are being conducted under the CSL License Agreement. Either party may terminate the Agreement on a product-by-product basis if certain patent challenges are made, on a product-by-product for material breaches, or due to the other party's bankruptcy. Upon termination of the CSL License Agreement, subject to certain exceptions, the licenses granted under the CSL License Agreement terminate. In addition, dependent upon the circumstances under which the CSL License Agreement is terminated, we or CSL have the right to continue the research, development, and commercialization of terminated products, including rights to certain data, for the continued development and sale of terminated products and, subject to certain limitations, obligations to make sales-based royalty payments to the other party.

If the CSL License Agreement were terminated and we had the right to continue the research, development, and commercialization of one or more terminated products, to fully exercise that right, we would need to expand our internal capabilities or enter into another collaboration, which, if we were able to do so, could cause significant delays that could prevent us from commercializing those products. Any alternative collaboration could be on less favorable terms to us. In addition, we may need to seek additional financing to support the research, development and commercialization of any terminated products, or alternatively we may decide to discontinue one or more terminated products, which could have a material adverse effect on our business. If the CSL License Agreement were terminated and CSL had the right to continue the development and commercialization of one or more terminated products, we would have no influence or input into those activities.

Under the CSL License Agreement, we are dependent upon CSL to successfully perform its responsibilities and activities, including the research, development and commercialization of M230 and research on other Fc multimer proteins. We do not control CSL's execution of its responsibilities or the resources it allocates to our products and product candidates. Our interests and CSL's interests may differ or conflict from time to time, or we may disagree with CSL's level of effort or resource allocation. CSL may internally prioritize our products and product candidates differently than we do or it may not allocate

sufficient resources to effectively or optimally execute its responsibilities or activities. If these events were to occur, our business would be adversely affected.

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

Because we have limited internal capabilities for late-stage product development, manufacturing, sales, marketing and distribution, we may need to enter into strategic alliances with other companies in addition to our current alliances with Sandoz, Mylan and CSL. In such alliances, we would expect our collaboration partners to provide substantial capabilities in clinical development, manufacturing, regulatory affairs, sales and marketing. We may not be successful in entering into any such alliances as a result of many factors including the following:

- competition in seeking appropriate collaborators;
- restrictions on future strategic alliances in existing strategic alliance agreements;
- a reduced number of potential collaborators due to recent business combinations of large pharmaceutical companies;
- inability to negotiate strategic alliances on a timely basis; and
- inability to negotiate strategic alliances on acceptable terms.

Even if we do succeed in securing such alliances, we may not be able to maintain them or they may be unsuccessful. We may be unable to maintain a strategic alliance if the development or approval of a product candidate that is the subject of the alliance is delayed or sales of an approved product that is the subject of the alliance are disappointing. The success of our collaboration agreements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Any such alliance would entail numerous operational and financial risks, including significant integration and implementation challenges that could disrupt our business and divert our management's time and attention. If we are unable to secure or maintain such alliances or if such alliances are unsuccessful, we may not have the capabilities necessary to continue or complete development of our product candidates and bring them to market, which may have an adverse effect on our business.

In addition to product development and commercialization capabilities, we may depend on our alliances with other companies to provide substantial additional funding for development and potential commercialization of our product candidates. These arrangements may require us to relinquish rights to some of our technologies, product candidates or products which we would otherwise pursue on our own. These alliances may also involve the other company purchasing a significant number of shares of our common stock. Future alliances may involve similar or greater sales of equity, debt financing or other funding arrangements. We may not be able to obtain funding on favorable terms from these alliances, and if we are not successful in doing so, we may not have sufficient funds to develop a particular product candidate internally or to bring product candidates to market. Failure to bring our product candidates to market will prevent us from generating sales revenue, and this may substantially harm our business. Furthermore, any delay in entering into these alliances could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. As a result, our business and operating results may be adversely affected.

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

A significant change in the business operations of, a change in the financial condition of, a change in senior executive management within, or a change in control of our third-party collaborators, or any future collaboration partners or third party manufacturers could have a negative impact on our business operations.

Since many of our product candidates are developed under collaborations or licenses with third parties, we do not have sole decision making authority with respect to commercialization or development of those product candidates. We have built relationships and work collaboratively with our third-party collaborators and manufacturers to ensure the success of our development and commercialization efforts. A significant change in the senior management team, a change in the financial condition or a change in the business operations, including a change in control or internal corporate restructuring, of any of our collaboration partners or third-party manufacturers, could result in delayed timelines on our products. In addition, we may have to re-establish working relationships and familiarize new counterparts with our products and business. Any such change may result in the collaboration partner or third party manufacturer internally re-prioritizing our programs or decreasing resources or funding allocated to support our programs. For example, in June 2016, Baxalta Incorporated and Shire announced the completion of a combination of Baxalta Incorporated and Shire, as a result of which Baxalta Incorporated became a wholly-owned subsidiary of Shire. On September 27, 2016, Baxalta gave us twelve months' prior written notice of the exercise of its right to terminate for its convenience the Baxalta Collaboration Agreement, and on December 31, 2016, we and Baxalta entered into an Asset Return and Termination Agreement pursuant to which the effective date of the Baxalta Termination was December 31, 2016. As a result, there could be changes or delays in the timing of the M923 program in connection with the return of the M923 program to us. Similar changes with respect to any of our other collaborators may negatively impact our business operations.

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 prohibit 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:

- delays in achievement of, or failure to achieve, program milestones that are associated with the valuation of our company or significant milestone revenue;
- failure of GLATOPA 20 mg/mL to sustain profitable sales or market share that meet expectations of securities analysts;
- adverse FDA decisions relating to our GLATOPA programs, including any FDA decision to delay approval of the GLATOPA 40 mg/mL ANDA until satisfactory resolution of the compliance observations in the FDA's February 2017

warning letter to Pfizer, Sandoz' third party fill/finish manufacturing partner for GLATOPA, and an FDA decision to require additional data, including requiring clinical trials, as a condition to the GLATOPA 40 mg/mL ANDA approval;

- litigation involving our company or our general industry or both, including litigation pertaining to the launch of our collaborative partners' or our competitors' products, including without limitation, a decision in the GLATOPA 40 mg/mL patent litigation or a competitors' related patent litigation that prevents the launch or delays the launch of our GLATOPA 40 mg/mL product;
- a decision in favor of, or against, Amphastar in our patent litigation suits, a settlement related to any case; or a decision in favor of third parties in antitrust litigation filed against us;
- announcements by other companies regarding the status of their ANDAs for generic versions of COPAXONE;
- FDA approval of other companies' ANDAs for generic versions of COPAXONE;
- marketing and/or launch of other companies' generic versions of COPAXONE;
- adverse FDA decisions regarding the development requirements for one of our biosimilar product 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;
- enactment of legislation 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 with respect to our technology-enabled generic product candidate, GLATOPA 40 mg/mL, or biosimilarity or interchangeability with respect to our biosimilar product candidates such as M923 or M834;
- demonstration of or failure to demonstrate the safety and efficacy for our novel product candidates;
- our inability to manufacture any products in conformance with cGMP or in sufficient quantities to meet the requirements for the commercial sale 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 product development and commercialization 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 biotechnology company securities specifically.

If any of these factors cause 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 significant 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 or other events at 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. For example, we are aware that several law firms have announced investigations of potential claims against the Company concerning possible violations of federal securities laws in connection with our February 17, 2017, announcement of the FDA warning letter to Sandoz' third party fill/finish manufacturing partner for GLATOPA. 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

Exhibit Number	Description	Incorporated by Reference to			
		Form or Schedule	Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Third Amended and Restated Certificate of Incorporation.	S-3	3.1	04/30/2013	333-188227
3.2	Fourth Amended and Restated By-Laws of the Registrant, adopted on March 14, 2017.	8-K	3.1	03/17/2017	000-50797
*+10.1	License and Option Agreement, by and between the Registrant and CSL Behring Recombinant Facility AG, dated as of January 4, 2017.				
*+10.2	Letter to the Registrant from CSL Limited, dated as of January 4, 2017.				
*+10.3	Amendment No. 1, effective as of March 20, 2017, to Asset Return and Termination Agreement, effective as of December 31, 2016, by and between the Registrant and Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH.				
*#10.4	Momenta Pharmaceuticals, Inc. Equity Award Retirement Policy.				
*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.INS	XBRL Instance Document.				
*101.SCH	XBRL Taxonomy Extension Schema Document.				
*101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
*101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
*101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
*101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				

* Filed herewith.

** Furnished herewith.

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

\# Management contract or compensatory plan or arrangement.

The following materials from the Registrant's Quarterly Report on Form 10-Q for the period ended March 31, 2017 , formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets at March 31, 2017 and December 31, 2016 , (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss for the three months ended March 31, 2017 and 2016 , (iii) the Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2017 and 2016 , and (iv) Notes to Unaudited, Condensed Consolidated Financial Statements.

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: May 5, 2017

By: /s/ Craig A. Wheeler

Craig A. Wheeler, President and Chief Executive Officer
(Principal Executive Officer)

Date: May 5, 2017

By: /s/ Scott M. Storer

Scott M. Storer, Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Confidential Treatment Requested by Momenta Pharmaceuticals, Inc.

LICENSE AND OPTION AGREEMENT

BY AND BETWEEN

MOMENTA PHARMACEUTICALS, INC.

AND

CSL BEHRING RECOMBINANT FACILITY AG

DATED AS OF J ANUARY 4, 2017

Confidential Portions of this Exhibit marked as [***] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

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LICENSE AND OPTION AGREEMENT

This License and Option Agreement (the " **Agreement** "), executed as of January 4, 2017 (the " **Execution Date** "), is made by and between Momenta Pharmaceuticals, Inc., a Delaware corporation (" **Momenta** "), with its principal place of business at 675 West Kendall Street, Cambridge, MA 02142 USA, and CSL Behring Recombinant Facility AG, a Swiss company (" **CSL** "), with its principal place of business at Wankdorfstrasse 10, 3000 Bern 22, Switzerland. Momenta and CSL may each be referred to individually as a " **Party** " or, collectively, the " **Parties** ".

RECITALS

A. Momenta is performing research in the area of recombinant Fc multimeric proteins to treat autoimmune disorders and invented the Initial Products.

B. CSL is engaged in the research, development, manufacture and commercialization of biotherapeutic products.

C. Momenta desires to grant to CSL and CSL desires to receive exclusive, worldwide licenses to research the Research Products and develop, manufacture and commercialize the Products.

D. CSL desires to grant to Momenta and Momenta desires to receive, by way of alternative consideration for the exclusive licenses granted herein, options to co-fund global development and U.S. commercialization costs for the Products and the Research Products in exchange for a share of the U.S. profits and losses for the Products on the terms and conditions set forth in this Agreement.

E. Momenta further desires to receive, and CSL desires to grant an option for Momenta to co-promote in the United States the Products for which it is co-funding global development and U.S. commercialization costs, on the terms and conditions set forth in this Agreement.

In consideration of the premises set forth above and the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Momenta and CSL agree as follows:

ARTICLE 1.
DEFINITIONS

The capitalized terms used in this Agreement (other than the headings of the Sections or Articles) have the following meanings set forth in this **Article 1** , or, if not listed in this **Article 1** , the meanings as designated in the text of this Agreement.

1.1 " **30% Co-Funding Option** " shall have the meaning set forth in **Section 4.1(b)** .

1.2 " **50% Co-Funding Option** " shall have the meaning set forth in **Section 4.1(a)** .

1.3 " **Accounting Standards** " means Generally Accepted Accounting Principles, as applicable, as consistently applied by a Party and its Affiliates, across product lines and in accordance with internal policies and procedures and Applicable Law (including the requirements of any securities exchange on which such Party is listed).

1.4 " **Acquirer** " – see "Change of Control".

1.5 " **Activities** " means Research Activities, Development Activities, Manufacturing Activities and Commercialization Activities, collectively.

1.6 " **[***]** " means, with respect to the [***], any event which is a [***] that would [***] of Development of the [***] for [***], or any [***] or [***] reasonably and objectively [***] to indicate a [***] of [***] for such Product that is detected prior to the date which is [***] after the [***] of such Product administered to the [***] in the [***].

1.7 " **Affiliate** " means any corporation, company, partnership, joint venture and/or firm that controls, is controlled by, or is under common control with, a Party. For purposes of the foregoing sentence, "control" means: (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.

1.8 " **Agreement** " means this License and Option Agreement.

1.9 " **Alleged Breaching Party** " shall have the meaning set forth in **Section 11.5(b)(i)** .

1.10 " **Alleging Party** " shall have the meaning set forth in **Section 11.5(b)(i)** .

1.11 " **Alliance Manager** " means an individual appointed by each Party to act as a primary point of contact between the Parties.

1.12 " **Annual Net Sales** " means, with respect to a Product, the Net Sales in a given calendar year in the Territory.

1.13 " **Anti-Corruption Laws** " shall have the meaning set forth in **Section 12.7** .

1.14 " **Applicable Law** " means all applicable provisions of any and all federal, national, state, provincial, and local statutes, laws, rules, regulations, administrative codes, ordinances, decrees, orders, decisions, injunctions, awards, judgments, permits and licenses of or from any governmental authorities (including Regulatory Authorities) relating to or governing a Party's obligations and rights under this Agreement.

1.15 " **[***]** " shall have the meaning set forth in **Section 7.6(c)** .

1.16 " **Assigning Party** " shall have the meaning set forth in **Section 13.3(a)** .

1.17 " **Bankruptcy Code** " means Title 11, United States Code.

1.18 " **Biosimilar Product** " means, with respect to a Product, any pharmaceutical product that: (a) receives marketing authorization pursuant to a Biosimilar Application made with respect to such Product and (b) is being sold by a Third Party (other than where such pharmaceutical product being sold by such Third Party is a Product which such Third Party is authorized to sell and is properly selling under this Agreement, including **Section 2.5** but not including products Commercialized following agreement pursuant to **Section 5.12** , unless the parties have agreed otherwise); and (c) is not purchased from or manufactured by CSL or any of its Affiliates or Sublicensees.

1.19 " **Biosimilar Application** " means, with respect to a Product, a submission to a Regulatory Authority for marketing authorization for a product claimed to be biosimilar or interchangeable to such Product, in the US under Section 351(k) of the BPCIA, or otherwise relying on the approval of such Product or data submitted in support of the prior approval of such Product, or any equivalent abbreviated regulatory process in another jurisdiction, in each case in accordance with Applicable Law in the jurisdiction in which the product is sought to be marketed and sold.

1.20 " **BLA** " means, with respect to a Product, a biologics license application that would satisfy the requirements of 21 C.F.R. § 601.2, as may be amended from time to time, or any non-U.S. equivalent thereof.

1.21 " **BPCIA** " means the Biologics Price Competition and Innovation Act of 2009, § 351(k) of the PHS Act, as may be amended, supplemented, or replaced.

1.22 " **Business Day** " a day other than Saturday or Sunday on which banking institutions in both New York, New York and Zurich, Switzerland are open for business.

1.23 " **Calendar Quarter** " means each of the three (3) month periods ending March 31, June 30, September 30 and December 31; provided , however , that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter shall extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.

1.24 " **C.F.R.** " means the U.S. Code of Federal Regulations.

1.25 " **Change of Control** " means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party (" **Acquirer** ") that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which an Acquirer, alone or together with its Affiliates, becomes the beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to an Acquirer of all or substantially all of such Party's business to which the subject matter of this Agreement relates.

1.26 " **Co-Funding** " means, with respect to any Product and at any particular time, that Momenta has exercised one of its Co-Funding Options and has not opted out of co-funding such Product as a result of (i) [***] out of co-funding [***] pursuant to **Section 4.2(a)** ; (ii) [***] out of co-funding [***] (including [***]) pursuant to **Section 4.2(b)** ; or (iii) [***] out of co-funding [***] specifically pursuant to **Section 5.2(g)** , and "Co-Fund" and "Co-Funded" are to be similarly construed.

1.27 " **Co-Funding Options** " means the 30% Co-Funding Option together with the 50% Co-Funding Option, and each a " **Co-Funding Option** ".

1.28 " **Co-Funding Option Effective Date** " means:

(a) in respect of the 50% Co-Funding Option, the date on which Momenta exercises its 50% Co-Funding Option in respect of the Products; and

(b) in respect of the 30% Co-Funding Option, the earlier of the date on which Momenta exercises its 30% Co-Funding Option and the date which is [***] after the date on which the [***] is [***] with the [***] of the Product in the [***] or [***] in respect of a Product.

1.29 " **Co-Promotion Agreement** " means a separate agreement setting out the Parties' rights and obligations with respect to co-promotion of Products which Momenta is Co-Funding, to be negotiated in good faith by the Parties within [***] after the date on which Momenta exercises its Co-Promotion Option.

1.30 " **Co-Promotion Option** " means an option to participate in the promotion of the Products in the United States.

1.31 " **[***]** " means any multimeric Fc construct comprising [***] or more Fc domains, optionally having [***] or more [***] and/or other [***] as compared to the [***] or [***] Fc constructs, provided that such construct may not consist of or incorporate a [***].

1.32 " **Commercialization** " and " **Commercialization Activities** " means all activities of using, marketing, promoting, distributing, importing, exporting, offering for sale and/or selling a pharmaceutical product

that has obtained Marketing Authorization (noting that some such activities may occur prior to the actual grant of Marketing Authorization) in the Territory. Commercialization Activities may include: (a) the creation and implementation of: (i) a [***] that is compliant with Applicable Law; (ii) a [***] including creation of [***] and initiatives; (iii) a [***], including selection and sequencing of [***] for [***] (but not the actual [***] and [***] of [***] pursuant to such strategy); (iv) development of a [***], including [***] and [***] (v) a [***], [***] and [***]; (vi) a [***] and [***]; (vii) a [***], including all [***] and [***] associated with the products; and (viii) a [***], including a product [***] and [***]; (b) [***] related to the product including [***], [***], management of [***]; (c) the design, creation and implementation of [***] and mechanisms; (d) the administration, operation and maintenance of [***] for promotion of product(s) in the Territory, sales bulletins and other [***] and [***] and [***], and [***] who support [***], including any activities of Momenta under the Co-Promotion Agreement; and (e) [***] (directly or indirectly) by the marketing authorization holder and [***]. For avoidance of doubt, (a) through (e) above sets forth examples of activities that may constitute "Commercialization Activities" rather than a [***] of [***] to be [***] by a Party. Commercialization does not include Research, Development or Manufacturing. When used as a verb, " **Commercialize** " means to engage in Commercialization.

1.33 " **Commercialization Expenses** " means, with respect to a Product, the costs actually incurred by or on behalf of a Party or its Affiliates, including labor costs and out-of-pocket costs (including relevant payments under [***] and/or [***] determined in accordance with **Section 7.6**) paid by a Party or its Affiliates to a Third Party or allocated to such Product after the Effective Date in connection with Commercialization of such Product in accordance with the applicable Product Work Plan, as determined from the books and records of the applicable Party and/or its Affiliates maintained in accordance with the Accounting Standards. For clarity, a Product's Commercialization Expenses excludes the Cost of Goods Sold for such Product and includes applicable expenses that are incurred by a Party pursuant to a Co-Promotion Agreement. Labor costs will be determined and allocation of expenses to any Product will be made as provided in **Schedule 1.33** .

1.34 " **Commercialization Plan** " means, with respect to a Product, a plan setting out, in detail that is [***] to the [***] of [***] or [***] of such Product, the Commercialization Activities and Manufacturing Activities that will be conducted in respect of such Product over the subsequent [***], where such plan shall set forth an [***] for [***] and Commercialization of such Product including, at the appropriate time, [***] by [***]; provided that such Commercialization Plan shall contain [***] of Commercialization Activities and Manufacturing Activities, and [***] therefore, for the [***] of the period covered and [***] for the [***] of such period, as adopted and revised as provided in **Section 5.3** .

1.35 " **Commercially Reasonable Efforts** " means, with respect to the performing Party, the carrying out of obligations of such Party in a diligent, expeditious and sustained manner as commonly practiced in the biopharmaceutical industry, including the [***] of a [***] of [***] and [***], and, in the case of [***] efforts to Develop and Commercialize Products, means a level of resources and efforts no less than the [***] and [***] that an [***] to products of [***] at a [***] of [***] or [***] in its [***], taking into account [***], [***] and [***] factors such as the [***], [***] of the [***] (including [***]), the [***] or other [***] of the Product or [***] Product, and the [***] involved, but without regard to other products (other than [***]) then being Developed or Commercialized [***]. In all cases, a Party's Commercially Reasonable Efforts requires that such Party: (a) [***] for [***] in a [***] to [***] who are [***] for [***] and [***] such [***] on an [***] basis; (b) [***] and [***] to [***] and [***] for carrying out such tasks; and (c) [***] and [***] decisions and [***] resources designed to [***] with respect to such [***]; in each case [***] with such Party's [***].

1.36 " **Confidential Information** " means: (a) all proprietary information and materials, patentable or otherwise, of a Party that is disclosed by or on behalf of such Party to the other Party pursuant to and in contemplation of this Agreement, including, without limitation, biological substances, sequences, formulations, techniques, methodology, equipment, data, reports, know-how, sources of supply, information disclosed in unpublished patent applications, patent positioning and business plans; and (b) any other information designated by the disclosing Party to the other Party in writing as confidential or proprietary, whether or not related to making, using or selling a Product. Notwithstanding the foregoing, the term "Confidential Information" shall not include information that: (w) is or becomes generally available to the public other than as a result of disclosure thereof by the receiving Party; (x) is lawfully received by the receiving Party on a non-confidential basis from a Third Party that is not, to the

receiving Party's knowledge, itself under any obligation of confidentiality or nondisclosure to the disclosing Party or any other Person with respect to such information; (y) is already known to the receiving Party at the time of disclosure by the disclosing Party; or (z) 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.

1.37 " **Control** " or " **Controlled** " means, with respect to any Intellectual Property of a Party or any of its Affiliates that the Party or its Affiliates (a) owns, has an interest in, or, other than pursuant to this Agreement, has a license to such Intellectual Property and (b) has the ability to grant access, a license or a sublicense to such Intellectual Property to the other Party as provided in this Agreement without violating an agreement with any Third Party. Notwithstanding anything in this Agreement to the contrary, a Party shall be deemed not to Control any Intellectual Property that is Controlled by an [***], or such [***] Affiliates (other than an Affiliate of such Party [***] to the [***]) (a) prior to the [***] of such [***], except to the extent that any such Intellectual Property was developed [***] such [***] through the use of the [***] technology, or (b) after such [***] to the extent that such Patents or know-how are developed or conceived by the [***] or its Affiliates [***] such [***] without using or incorporating any Intellectual Property of the [***] or its Affiliates [***] to such [***].

1.38 " **Cost of Goods Sold** " means, with respect to a Product, the aggregate of each Party's and its Affiliates' cost to Manufacture, perform quality control and assurance activities, test, package and label and release such Product for commercial use, in all cases determined from the books and records of such Party or its Affiliates maintained in accordance with the Accounting Standards, which costs may include (but not necessarily be limited to) the following:

(a) the [***] of [***]; variable and fixed production costs, including factory overhead; purchase price variances; [***] revaluations, including [***] destroyed or written-off; change in value of [***] provisions; production variances; Manufacturing plant labor; a [***] of plant overhead expenses (including insurance, facility, and support staff personnel); materials and supplies; maintenance; discards; depreciation and amortization;

(b) payments to Third Parties for [***] or [***] necessary for, or [***] and/or [***] determined in accordance with [***], for the commercial Manufacture, performance of quality control and assurance activities, testing, releasing, packaging and/or labeling may be treated as part of the Costs of Goods Sold for such Product and then such amounts shall not be included in any [***] payable under [***]; and

(c) with respect to any newly constructed or other dedicated Manufacturing facility, whether such facility is owned by a Party or a Third Party, that will be utilized in the Manufacture of a Product, if a Party determines it will build or utilize a facility with [***] relative to the [***] for the Product(s) to be Manufactured in such facility, any decision to account for plant [***] for such facility [***] such [***] in the computation of Cost of Goods Sold must be approved by the Parties.

1.39 " **Cover** ", " **Covering** " or " **Covered** " means, with respect to any Patent Right, that the manufacture, use, offer for sale, sale or import of any article or composition of matter, or the practice of any process or method, infringes at least one (1) Valid Claim of such Patent Right (or, in the case of a Valid Claim that has not yet issued, would infringe such Valid Claim if it were to issue without modification).

1.40 " **[***]** " means the [***].

1.41 " **CSL** " means CSL Behring Recombinant Facility AG, a Swiss company, with its principal place of business at Wankdorfstrasse 10, 3000 Bern 22, Switzerland.

1.42 " **CSL Indemnitees** " shall have the meaning set forth in **Section 9.2** .

1.43 " **CSL Intellectual Property** " means CSL Know-How and CSL Patent Rights, collectively.

1.44 " **CSL Know-How** " means any Know-How that either (a) is Controlled by CSL or its Affiliates on the Effective Date or (b) comes within CSL's or its Affiliates' Control during the Term, including CSL's or its Affiliates' rights in Joint Know-How and CSL Sole Inventions.

1.45 " **CSL Losses** " shall have the meaning set forth in **Section 9.2** .

1.46 " **CSL Patent Rights** " means Patent Rights, including CSL's or its Affiliates' rights in Joint Patent Rights, to the extent that they (a) Cover CSL Know-How, a Product or a [***] Product, and (b) are Controlled by CSL or its Affiliates.

1.47 " **CSL Sole Inventions** " means Sole Inventions made solely by CSL or its Affiliates, or CSL's or its Affiliates' employees, agents or consultants.

1.48 " **Development** " and " **Development Activities** " means all activities either related to or in furtherance of the creation or scientific or technical improvement of a pharmaceutical product, or which are related to or in furtherance of obtaining regulatory approvals of such product anywhere in the Territory, whether such activities are conducted prior to the filing of an application for marketing authorization of such product or thereafter. Development Activities may include but are not limited to (a) all activities related to [***] (including [***] to [***] any [***]), (b) [***]; (c) [***], (d) [***] and [***], (e) [***], (f) all [***] activities including [***] development, (g) [***], (h) [***], (i) [***] including [***] and [***], (j) submission and management of [***], (k) [***] or [***], including [***] of [***] or [***] for [***], maintaining such [***] and otherwise handling [***], (l) [***], and (m) [***]. For avoidance of doubt, (a) through (m) above sets forth examples of activities that would constitute "Development Activities" [***] a list of [***]. Development does not include Research, Manufacturing or Commercialization. When used as a verb, " **Develop** " means to engage in Development.

1.49 " **Development Expenses** " means, with respect to a Product, the costs actually incurred by or on behalf of a Party or its Affiliates, including labor costs and out-of-pocket costs paid by a Party or its Affiliates to a Third Party (including relevant payments under [***] and/or [***] determined in accordance with **Section 7.6**) or [***] to such Product after the Effective Date in connection with the Development of such Product in accordance with the applicable Product Work Plan, as determined from the books and records of the applicable Party and/or its Affiliates maintained in accordance with the Accounting Standards. Labor costs will be determined and [***] to any Product will be made as provided in **Schedule 1.33** .

1.50 " **Development Plan** " means, with respect to a Product, a Development plan that sets forth, [***] that is [***] to the [***] of [***] of such Product and otherwise in accordance with [***] and [***] and [***], the Development Activities that will be undertaken in respect of such Product in order to obtain Marketing Authorization; provided that such Development Plan shall contain [***] at any [***] that is [***] the [***] of [***] that [***] has [***] for its [***] and [***], as adopted and revised as provided in **Section 5.2** . A written description of those [***] has been provided by CSL to Momenta prior to the Execution Date.

1.51 " **Development Approval Date** " means, with respect to any [***] Product, the date on which CSL gives notice of its decision to select such [***] Product for Development as a Product under this Agreement, as provided in **Section 5.1(d)** .

1.52 " **Disputed Matter** " means a bona fide dispute that arises in relation to the Parties' rights and obligations under this Agreement.

1.53 " **Dollars** " or " **$** " means the legal tender of the United States.

1.54 " **[***]** " means the [***] of a [***] of [***].

1.55 " **Effective Date** " means the HSR Clearance Date.

1.56 " **EMA** " or " **European Medicines Agency** " means the EU agency for the evaluation of medicinal products, or any successor entity.

1.57 " **Enforcement Intellectual Property Rights** " shall have the meaning set forth in **Section 7.4(a).**

1.58 " **EU** " means the European Union.

1.59 " **Execution Date** " shall have the meaning set forth in the Preamble.

1.60 " **FDA** " or " **Food and Drug Administration** " means the U.S. Food and Drug Administration, or any successor entity.

1.61 " **Final Decision-Making Authority** " means the authority to make final decisions granted to CSL by the final sentence of **Section 6.7** (Review and Approval by JSC).

1.62 " **First Commercial Sale** " means, with respect to any Product, the [***] sale of such Product by CSL, its Sublicensee or any of their respective Affiliates to a Third Party in a country in the Territory for use or consumption by the general public in such country following receipt of Marketing Authorization for such Product in such country.

1.63 " **[***] Product** " means that Collaboration Compound under development by Momenta designated as "M230", a [***] human [***] Fc construct more specifically described, and having the [***] set out, in written disclosure from Momenta to CSL on or before the Execution Date.

1.64 " **[***]** " shall have the meaning set forth in **Section 11.2(a)** .

1.65 " **[***] Product** " means that [***] under development by Momenta as a [***] form of the [***] as more specifically described, and having the [***] set out, in written disclosure from Momenta to CSL on or before the Execution Date.

1.66 " **GCP** " or " **Good Clinical Practice** " means the standards of good clinical practice as are required by governmental agencies in countries in which the Products are intended to be sold under this Agreement.

1.67 " **GLP** " or " **Good Laboratory Practice** " means the standards of good laboratory practice as a required by governmental agencies in countries in which the Products are intended to be sold under this Agreement.

1.68 " **GLP Toxicology Commencement** " means, with respect to a Product or a [***] Product, [***] of the [***] with such Product or [***] Product in an [***] intended to support the safety of such Product or [***] Product in accordance with GLP as is required to [***] a [***].

1.69 " **GMP** " or " **Good Manufacturing Practice** " means the standards of good manufacturing practice as are required by governmental agencies in countries in which the Products are intended to be sold under this Agreement.

1.70 " **HSR Act** " shall have the meaning set forth in **Section 13.12** .

1.71 " **HSR Clearance Date** " means the date on which the antitrust clearance under the HSR Act has been obtained which, for the avoidance of doubt, means that the waiting period provided by the HSR Act has terminated or expired without any action by any government agency or challenge to the termination.

1.72 " **Indication** " means a distinct condition in humans for which a separate Marketing Authorization is required.

1.73 " **Infringement** " means (i) any actual or threatened infringement or misappropriation of any CSL Intellectual Property, Momenta Intellectual Property or Joint Intellectual Property by a Third Party in the Territory, or (ii) any CSL Intellectual Property, Momenta Intellectual Property or Joint Intellectual Property is subject to an invalidation, cancellation, opposition or other similar action (including any administrative or judicial action whether or not there is current or anticipated infringement or misappropriation), or a declaratory judgment action arising from such infringement or misappropriation.

1.74 " **Initial Press Release** " shall have the meaning set forth at **Section 8.2** .

1.75 " **Initial Products** " means the First Product and the [***] Product from and after its Development Approval Date, collectively.

1.76 " **Intellectual Property** " means Know-How and Patent Rights.

1.77 " **Joint Intellectual Property** " means Joint Know-How and Joint Patent Rights, collectively.

1.78 " **Joint Inventions** " means all inventions made jointly by both (a) one or more employees, agents and consultants of CSL and its Affiliates (or any Third Party or Third Parties acting on any of their behalf), and (b) one or more employees, agents and consultants of Momenta and its Affiliates (or any Third Party or Third Parties acting on any of their behalf).

1.79 " **Joint Know-How** " means any Know-How that is developed or acquired jointly by the Parties in connection with their collaborative activities pursuant to this Agreement, including Joint Inventions.

1.80 " **Joint Patent Rights** " means Patent Rights that Cover Joint Know-How.

1.81 " **Joint Steering Committee** " or " **JSC** " means the joint steering committee established pursuant to **Section 6.1** composed of senior members from each Party, including one Alliance Manager, to oversee and manage the Research of [***] Products and the Development, Manufacturing and Commercialization of Products.

1.82 " **Know-How** " means all inventions, discoveries, data, processes, methods, techniques, materials, technology, results, analyses, laboratory, non-clinical and clinical data, commercial materials, information, materials or other know-how, whether proprietary or not and whether patentable or not, including without limitation ideas, concepts, formulae, methods, procedures, designs, compositions, plans, documents, works of authorship, compounds, biological materials, pharmacology, toxicology, drug stability, manufacturing and formulation methodologies and techniques, absorption, distribution, metabolism and excretion studies, clinical and non-clinical safety and efficacy studies, marketing studies and materials (including patient marketing materials), training materials and digital content from product websites.

1.83 " **Losses** " means any and all liabilities, penalties, damages costs, fines, and expenses (including reasonable attorneys' fees and other litigation expenses) associated with Products to the extent such Losses are not otherwise allocated either to CSL under **Section 9.1** as Momenta Losses or to Momenta as CSL Losses under **Section 9. 2** .

1.84 " **Major Countries** " means the U.S., [***] and [***].

1.85 " **Manufacturing" and "Manufacturing Activities** " means, with respect to a product, to make or have made such product, including without limitation, all activities involved in the [***], and [***] of the product for [***], development of a [***], the manufacture of the [***] for the product, the [***] of the [***] for the product and the cost of any [***] or [***] of the biopharmaceutical product. For avoidance of doubt, the foregoing set forth examples of activities that would constitute "Manufacturing Activities" rather than a list of [***] to be [***] a [***]. Manufacturing does not include Research, Development or Commercialization. When used as a verb, " **Manufacture** " means to engage in Manufacturing.

1.86 " **Manufacturing Expenses** " means, with respect to a Product, the costs actually incurred by or on behalf of a Party or its Affiliates, including labor costs, depreciation costs, and out-of-pocket costs paid to a Third Party or allocated to such Product after the Effective Date, in connection with Manufacturing of such Product by or on behalf of a Party, as determined from the books and records of the applicable Party and/or its Affiliates maintained in accordance with the Accounting Standards. Manufacturing Expenses includes expenses under [***] and [***] determined in accordance with **[***]** . In addition, with respect to any newly constructed or other dedicated Manufacturing facility, whether such facility is owned by a Party or a Third Party, that will be utilized in the Manufacture of a Product, if a Party determines it will [***] or [***] a [***] with [***] to the [***] for the Product(s) to be Manufactured in such facility, any decision to account for plant [***] for such [***] in [***] of such [***] in the [***] of [***] must be [***] the [***], For clarity, a Product's Manufacturing Expenses includes the Cost of Goods Sold for such Product.

1.87 " **Marketing Authorization** " means the grant of registration approval or license for the selling or marketing of a Product in any particular country or region in the Territory by the responsible Regulatory Authority.

1.88 " **Momenta** " means Momenta Pharmaceuticals, Inc., a Delaware corporation, with its principal place of business at 675 West Kendall Street, Cambridge, MA 02142 USA.

1.89 " **Momenta Indemnitees** " shall have the meaning set forth in **Section 9.1** .

1.90 " **Momenta Intellectual Property** " means Momenta Know-How and Momenta Patent Rights, collectively.

1.91 " **Momenta Know-How** " means any Know-How that either (a) is Controlled by Momenta or its Affiliates on the Effective Date or (b) comes within Momenta's or its Affiliates' Control during the Term, including Momenta's or its Affiliates' rights in Joint Know-How and Momenta Sole Inventions.

1.92 " **Momenta Losses** " shall have the meaning set forth in **Section 9.1** .

1.93 " **Momenta Patent Rights** " means (i) Patent Rights listed in **Schedule 1.93** and (ii) any other Patent Rights, including Momenta's or its Affiliates' rights in Joint Patent Rights, to the extent that they (a) Cover Momenta Know-How, a Product or a [***] Product, and (b) are Controlled by Momenta or its Affiliates.

1.94 " **Momenta Sole Inventions** " means Sole Inventions made solely by Momenta or its Affiliates, or Momenta's or its Affiliates' employees, agents or consultants.

1.95 " **[***]"** has the meaning given to it in **Section 7.6(b)** .

1.96 " **Net Sales** " means, with respect to a Product, the [***] by a Party or its Affiliates or Sublicensees to Third Parties (whether an end-user, a distributor or otherwise) for sales of such Product within the Territory, less the following deductions, all as determined from the books and records of a Party, its Affiliates or Sublicensees maintained in accordance with the Accounting Standards:

(a) customary trade and quantity discounts incurred and customary distribution rebates;

(b) amounts incurred due to returns of Products previously sold as reflected in written invoices (and not to exceed the original invoice amount);

(c) shipping, freight and insurance, to the extent separately invoiced and charged;

(d) credits, allowances and rebates actually given pursuant to federal, state and/or government-mandated programs that require a manufacturer or distributor rebate (including Medicare and Medicaid); and

(e) value added or import/export taxes, sales taxes, excise taxes or customs duties, to the extent applicable to such sale, and included in the invoice in respect of such sale and actually paid.

In the case of any sale of a Product between or among a Party or its Affiliates or Sublicensees for resale, Net Sales shall be calculated as above only on the [***] on the first arm's length sale thereafter to a Third Party other than a Sublicensee. If no such separate sales are made, Net Sales shall be determined by the Parties in good faith. If the consideration for Products includes any non-cash element, or if Products are transferred by the selling Party, its Affiliate, or a respective Sublicensee in any manner other than an arms-length, [***] sale, then, in any such transaction, the Net Sales applicable to such transaction shall be the fair market value for the applicable quantity for the period in question in the applicable country of the Territory. The fair market value shall be determined, wherever possible, by reference to the average selling price of the relevant Product in arm's length transactions in the relevant country in the Territory. Any Product transferred in connection with clinical and non-clinical research or clinical trials, Product promotional samples, compassionate sales or use, or indigent patient programs shall not be counted toward Net Sales; except that any Product sold as part of a named patient use program (or similar program where a Product can be sold in a country prior to Regulatory Approval being obtained for such Product in such country) will be counted toward Net Sales.

Each Party agrees, on behalf of itself and its Affiliates and Sublicensees, not to use any Product as a loss leader. Each Party also agrees that if it or its Affiliate or Sublicensee prices a 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 for any discount which was given to a customer that was in excess of customary discounts for such Product (or, in the absence of relevant data for such Product, other similar products under similar market conditions) by reversing such excess discount, if such discount was given in order to gain or maintain sales of other products.

If any Product is sold in combination with one or more other products (*e.g.* , a delivery device) or active ingredients which are not the subject of this Agreement (as used in this definition of Net Sales, a " **Combination** "), then the [***] for that Product shall be calculated by multiplying the [***] for such Combination by the fraction A/(A+B), where "A" is the [***] for the Product sold separately and "B" is the [***] for the other product or active ingredient(s) sold separately. If the other product or active ingredient is not sold separately, then the [***] for that Product shall be calculated by multiplying the [***] for the Combination by the fraction A/C, where "A" is the [***] for the Product, if sold separately, and "C" is the [***] for the Combination.

1.97 " **Net Sales Statement** " means a written report reflecting the accrual of Net Sales during the just-ended Calendar Quarter on a country-by-country and Product-by-Product basis [***] a [***] of Net Sales of such Product from [***], including [***] on [***] to be [***] in determining Net Sales pursuant to **Section 1.96** , [***] a [***] of the applicable [***], [***] and [***] for such [***].

1.98 " **New Intellectual Property** " means all CSL Intellectual Property and all Momenta Intellectual Property that is not Joint Intellectual Property (a) arising out of the Parties' Activities conducted pursuant to the Research Plan and (b) in the event of a termination under the provisions of **Section 11.2(b)** or **Section 11.3** , arising out of the Development Plan prior to the [***] of the [***] for the [***].

1.99 " **Opt-Out Effective Date** " means the date on which an Opt-Out Notice given by Momenta to CSL becomes effective.

1.100 " **Opt-Out Notice** " shall have the meaning set forth in **Section 4.2(a).**

1.101 " **Party** " means CSL or Momenta, and or " **Parties** " means both of them.

1.102 " **Patent Rights** " means any and all rights provided by (a) U.S. or non-U.S. patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, and all patents granted thereon, (b) all U.S. or non-U.S. patents, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, and (c) any other form of government-issued right substantially similar to any of the foregoing.

1.103 " **Person** " means any individual, partnership, joint venture, limited liability company, corporation, firm, trust, association, unincorporated organization, Regulatory Authority or any other entity not specifically listed herein.

1.104 " **Phase I** " in reference to a clinical trial means a trial defined in 21 C.F.R. § 312.21(a), as may be amended from time to time, or any non-U.S. equivalent thereof.

1.105 " **Phase II** " in reference to a clinical trial means a trial defined in 21 C.F.R. § 312.21(b), as may be amended from time to time, or any non-U.S. equivalent thereof.

1.106 " **Phase III** " in reference to a clinical trial means a trial defined in 21 C.F.R. § 312.21(c), as may be amended from time to time, or any non-U.S. equivalent thereof, or if any Phase II clinical trial is a registration enabling pivotal clinical trial and a Phase III trial is not needed, then " **Phase III** " in reference to a clinical trial shall be deemed to refer to such Phase II registration enabling pivotal clinical trial.

1.107 " **Phase IV** " in reference to a clinical trial means a trial defined in 21 CFR § 312.85, as may be amended from time to time, or any non-U.S. equivalent thereof.

1.108 " **PHS Act** " means the U.S. Public Health Service Act, as may be amended from time to time.

1.109 " **Prior Confidentiality Agreement** " means the Confidentiality Agreement dated [***] between Momenta and [***], as amended.

1.110 " **Prior Material Transfer Agreement** " means the Material Transfer Agreement dated [***] between Momenta and [***].

1.111 " **Product** " means the First Product or any [***] Product from and after its Development Approval Date.

1.112 " **Product Domain Name** " means a domain name selected by CSL for the purpose of Commercializing a Product in the Territory.

1.113 " **Product Trademark** " means a trademark selected by CSL for the purpose of Commercializing a Product in the Territory.

1.114 " **Product Work Plan** " means, with respect to a Product, the Development Plan together with the Commercialization Plan.

1.115 " **Profit(s)** " means [***] plus [***] minus [***], provided that should any expense fall within the definition of [***] and [***] a permitted deduction for the purpose of calculating [***], such expense shall only be [***].

1.116 " **Program Expenses** " means Research Expenses, Development Expenses, Manufacturing Expenses and Commercialization Expenses.

1.117 " **Regulatory Approval** " means, with respect to a country, [***], [***] and regulatory authorizations [***] to [***], market and sell a Product in such country as granted by the relevant Regulatory Authority, and includes Marketing Authorization.

1.118 " **Regulatory Authority** " means, in a country, any applicable government authority, agency, legislative body, commission or other instrumentality of any national or territorial government or any supranational body which is responsible for granting approvals for the sale, use and/or manufacture of pharmaceutical products in that country or region, including the FDA, the EMA and any corresponding national or regional regulatory authorities.

1.119 " **Regulatory Exclusivity** " means data, market or other regulatory exclusivity (as distinct from and excluding any exclusivity arising under Patent Rights) for an [***] Product in a country or region in the Territory under applicable laws, rules and regulations in such country or region, including, without limitation, (a) any such exclusivity provided in countries in the EU under national laws and regulations implementing EC Directives 2004/27/EC and 2001/83/EC, (b) U.S. exclusivity periods such as U.S. biologic exclusivity, pediatric exclusivity, orphan drug exclusivity, and the Hatch-Waxman data exclusivity or (c) any analogous laws or regulations in other countries in the Territory.

1.120 " **Regulatory Submission** " means any application for Regulatory Approval, notification, and other submission made to or with a Regulatory Authority that is [***] to Develop, Manufacture, distribute or Commercialize the Product in a particular country, whether made before or after a Regulatory Approval in the country. Regulatory Submissions include, without limitation, investigational new drug applications, clinical trial applications and BLAs or imported drug license (IDL) applications, and amendments, renewals and supplements to any of the foregoing and their non-U.S. counterparts, [***] for [***] and [***], and all proposed labels, labeling, package inserts, monographs, and packaging for the Product.

1.121 " **Reimbursement and Co-Funding Report** " means a cost reimbursement and/or cost/profit share report meeting the requirements set out in **Section 4.3(c)** , and accompanied [***] and [***] to [***] each Party's financial reporting obligations, independent auditor requirements and obligations under the Sarbanes-Oxley Act (or any equivalent law of another country) that calculates the share of each Party's aggregate [***] and the [***] and [***] to be allocated to each Party for each Product for such Calendar Quarter.

1.122 " **Research** " or " **Research Activities** " means all activities either related to or in furtherance of the creation or scientific or technical improvement of a biopharmaceutical product up to [***] for such product (and, for the avoidance of doubt, may include activities that would otherwise be defined as Manufacturing and Development activities if they were performed after [***]).

1.123 " **Research Expenses** " means, with respect to a [***] Product, the costs actually incurred by or on behalf of a Party or its Affiliates, including labor costs and out-of-pocket costs paid by a Party or its Affiliates to a Third Party or allocated to such [***] Product after the Effective Date in connection with the Research of such [***] Product in accordance with the applicable Research Plan, as determined from the books and records of the applicable Party and/or its Affiliates maintained in accordance with the Accounting Standards. Labor costs will be determined and allocation of expenses to any [***] Product will be made as provided in **Schedule 1.33** . Research Expenses includes expenses under [***] and [***] determined in accordance with **Section 7.6.**

1.124 " **Research Plan** " means the plan setting out the Parties' Research Activities, adopted and revised as provided in **Section 5.1(a)** .

1.125 " **Research Product** " means the [***] Product and any other [***] which is generated out of or otherwise forms a part of the activities to be undertaken pursuant to the Research Plan.

1.126 " **Royalty Period** " means, with respect to an Initial Product, the longer of the following periods, in each case on a [***] basis: (A) the period during which the sale or use of such Initial Product [***] would infringe a granted Valid Claim of [***] or [***] in [***] where (i) the Valid Claim is part of the [***] of [***] set out in the [***] in the [***] of [***] and (ii) for the purpose of determining whether such Valid Claim is infringed, no effect is given to any license granted under this Agreement or to [***] of [***] with respect to any Joint Patent Right, (B) the period during which such Product is [***] by [***] in [***]; and (C) [***] from First Commercial Sale of such Product in [***].

1.127 " **Sarbanes-Oxley Act** " means the U.S. Sarbanes-Oxley Act of 2002, as may be amended from time to time.

1.128 " **[***]** " means a multimeric Fc construct that consists of [***] or [***] to [***] or [***], wherein the Fc construct [***] or [***] or [***] and the [***] or [***] or [***] the [***] to a [***] and/or [***] other than a [***]. For the purpose of this definition, [***] means a [***] of an [***] that contains [***], and part of [***].

1.129 " **Sole Inventions** " means all inventions made solely by a Party or its Affiliates, or such Party's or its Affiliates' employees, agents or consultants.

1.130 " **Sub-Committee** " means a sub-committee formed by the JSC, with an equal number of representatives from CSL and Momenta, to address specific issues in greater detail.

1.131 " **Sublicense Revenue** " means all consideration received by a Party or its Affiliates with respect to rights granted to a Third Party(ies) to Develop or Commercialize any Product for sale in the relevant country in the Territory, but excluding: (a) consideration received by such Party or its Affiliates as payments [***] for performing [***] or [***] undertaken by such Party or its Affiliates for, or in collaboration with, such Third Party(ies) or their Affiliates; (b) consideration received by such Party and/or its Affiliates from such Third Party(ies) or their Affiliates as the [***] for such Party's or any of its Affiliates' [***] or [***], except that consideration that [***] the [***] of [***] or [***]; and (c) consideration paid by such Third Party(ies) to such Party or its Affiliates to [***] of such Product (provided , however , that any consideration [***] the [***].

1.132 " **Sublicensee** " means a Third Party that is granted a license, sublicense, covenant not to sue, or other grant of rights under this Agreement pursuant to the terms of this Agreement or otherwise granted rights with respect to any Product.

1.133 " **Summary Statement** " means a written report provided in accordance with **Section 4.3(b)** reflecting the accrual of Program Expenses and Net Sales, as applicable, during the just-ended Calendar Quarter on a [***] Product-by-[***] Product (where possible) and Product-by-Product basis.

1.134 " **Technology Package** " means all relevant documents relating to the Intellectual Property, regulatory information, biological materials, manufacturing and CMC and other materials owned and/or Controlled by Momenta, necessary for CSL to exercise its rights under the license, to be included in the Technology Transfer Plan.

1.135 " **Technology Transfer Plan** " means the written transfer plan, an outline of the CMC elements of which is attached hereto as **Schedule 1.135** , [***] will be [***] to [***] after the [***] and which will form [***], which sets forth the activities of each Party relating to the transfer of the Technology Package and the timelines thereof, as may be updated from time to time until completion of all contemplated activities.

1.136 " **Term** " shall have the meaning set forth in **Section 11.1** .

1.137 " **Termination Date** " means the date this Agreement is terminated as provided for under each circumstance of termination in **Article 11** .

1.138 " **Territory** " means all countries of the world.

1.139 " **Third Party** " means any Person other than Momenta or CSL or any Affiliate of either Party.

1.140 " **Third Party Intellectual Property** " means Third Party Patent Rights, Know-How, Trademarks, domain names or other intellectual property rights.

1.141 " **Third Party License** " shall have the meaning set forth in **Section 7.6** .

1.142 " **Trademark** " means all trademarks, service marks, trade names, brand names, sub-brand names, trade dress rights, product configuration rights, certification marks, collective marks, logos, taglines, slogans, designs or business symbols and all words, names, symbols, colors, shapes, designations or any combination thereof that

function as an identifier of source or origin or quality, whether or not registered, and all statutory and common law rights therein, and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.143 " **Transferee** " shall have the meaning set forth in **Section 13.3(a)** .

1.144 " **United States** " or " **U.S.** " means the United States of America, and its territories, districts and possessions.

1.145 " **U.S.C.** " means the United States Code.

1.146 " **Valid Claim** " means: (a) a claim in issued Patent Rights that has not: (i) expired or been canceled; (ii) been declared invalid by an unreversed and unappealable (or unappealed) decision of a court or other appropriate body of competent jurisdiction; (iii) been admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (iv) been abandoned by mutual written agreement of the Parties; or (b) a claim under an application for Patent Rights that has not been canceled, withdrawn from consideration, finally determined to be unallowable by the applicable governmental authority or court for whatever reason (and from which no appeal is or can be taken) or abandoned.

For the purposes of the definition of [***] and for [***] to [***], Valid Claims [***] to the subset of Patent Rights Controlled by a Party to the extent such Patent Rights are owned by, are [***] or are exclusive license rights, held by a Party or the Parties with respect to the [***] of [***] or [***] of [***] of the relevant Product.

In the case of the First Product, the subset of Patent Rights Controlled by Momenta meeting these criteria at the Execution Date are the Patent Rights listed in **Schedule 1.93** and listed under the Momenta internal references of [***] and [***].

ARTICLE 2.
LICENSES

2.1 **Licenses to CSL** . Subject to the terms and conditions of this Agreement, as of the Effective Date, Momenta hereby grants to CSL the following:

(a) Product License . A royalty-bearing, exclusive, nontransferable (except as set forth in **Section 13.3**) license, with the right to grant sublicenses as described in **Section 2.5** , under the Momenta Intellectual Property and Momenta's rights in the Joint Intellectual Property to Research, Develop, Manufacture and Commercialize Products in the Territory.

(b) Research License . A royalty-free, exclusive, nontransferable (except as set forth in **Section 13.3**) license, with the right to grant sublicenses as described in **Section 2.5** , under the Momenta Intellectual Property and Momenta's rights in the Joint Intellectual Property for purposes of researching (i) potential [***] Products and (ii) the [***] Products in the Territory.

(c) [***]. The Parties acknowledge and agree that the license and sublicense rights granted by Momenta to CSL and CSL to Momenta under this Agreement [***] be [***] a [***] the [***] in [***] between the Parties or the [***] or [***] when exercised in compliance with the terms of this Agreement.

2.2 **Licenses to Momenta** . Subject to the terms and conditions of this Agreement, as of the Effective Date, CSL hereby grants to Momenta: a limited, royalty-free, non-exclusive, nontransferable (except as set forth in **Section 13.3**) license, with the right to grant sublicenses as described in **Section 2.5** , under the Momenta Intellectual Property, the CSL Intellectual Property and CSL's rights in the Joint Intellectual Property to the extent necessary and for the purpose of enabling Momenta (i) to research potential [***] Products (ii) to perform Activities pursuant to the Research Plan or a Product Work Plan and (iii) to undertake research pursuant to **Section 5.14** . In addition,

CSL grants to Momenta a limited, non-exclusive, non-transferrable license solely relating to the New Intellectual Property to engage in non-commercial research and development subject to the terms of this Agreement.

2.3 **Joint Intellectual Property** . Subject to the terms and conditions of this Agreement including in relation to management and enforcement of Intellectual Property as set out in **Article 7** and, as applicable, any Co-Promotion Agreement, as of the Effective Date, each Party hereby grants the other Party a world-wide, non-exclusive, perpetual, royalty-free, fully paid up, freely sublicensable right and license under its interest in the Joint Intellectual Property to exploit products other than Products (a) anywhere in the world and (b) without compensating or accounting to the other Party.

2.4 **Use of Third Party Contractors** . Subject to the terms of this Agreement, either Party may perform any specific Activities for which it is responsible under this Agreement through subcontracting to a Third Party contractor and may grant a sublicense of the rights granted hereunder to any such Third Party contractor; provided that where [***] seeks to engage such subcontractor, [***] shall first obtain [***] to the appointing of such sub-contractor and, where necessary, the granting of such sublicense, provided further , that if a Third Party contractor is specified or otherwise authorized generally for categories of activity in an approved Product Work Plan, then [***] to [***] the [***] and [***] of a [***] to such Third Party contractor solely for the purposes set forth in such Product Work Plan.

2.5 **[***]** . Except as permitted in **[***]** in respect of [***], each Party may only [***] the [***] to such Party under **[***]** , and **[***]** with the other Party's [***]. Any [***] granted by either Party pursuant to this Agreement will be [***] the [***] of [***]. In addition, each Party will [***], with respect to the Products and the [***] Products or [***], to [***] or [***] the [***] that such [***] may [***] in connection with its activities with respect to the Products and the [***] Products that would constitute [***] or [***] if arising [***] or [***] activities, respectively, so that any such Intellectual Property will be Controlled by the [***] Party for purposes and to the extent of the [***] to the other Party provided by **Sections 2.1** and **2.2** above. [***], either Party may grant [***] of its rights hereunder to any Affiliate; provided that such Party remains primarily liable for the performance hereunder of any of its Affiliates.

2.6 **Technology Transfer** .

(a) **General** . Momenta will use Commercially Reasonable Efforts to transfer the Technology Package to CSL:

(i) in accordance with the outline of the Technology Transfer Plan attached hereto as **Schedule 1.135** where both activities and timeframes are specified in that Schedule; and

(ii) otherwise in accordance with the Technology Transfer Plan, and both Parties will perform their respective activities under and in accordance with the Technology Transfer Plan (with the Technology Transfer Plan to prevail over the outline in the event of any inconsistency).

(iii) In exercising such Commercially Reasonable Efforts a Party shall not be responsible for any delay or failure to achieve an objective to the extent such delay or failure is caused by the actions of the other Party.

(b) **Technology Transfer Plan** . Momenta will use Commercially Reasonable Efforts to execute the Technology Transfer Plan in an [***] and [***] and in accordance with **Schedule 1.135** (as modified (if applicable) by the agreed Technology Transfer Plan) In [***] the [***], Momenta will use Commercially Reasonable Efforts to transfer to CSL [***] under the Technology Package which are specified in **Schedule 1.135** within [***] after the Effective Date and the Parties shall use Commercially Reasonable Efforts to complete the Technology Transfer Plan [***] with the goal of completing all activities under the Technology Transfer Plan no later than [***] after the Effective Date.

2.7 **Retained Rights** . Any rights of Momenta not expressly granted to CSL under the provisions of this Agreement shall be retained by Momenta and any rights of CSL not expressly granted to Momenta under the provisions of this Agreement shall be retained by CSL.

2.8 **[***]** . For the avoidance of doubt, in the event either Party [***] or [***], or has an opportunity to [***] or [***], directly or by way of an [***] to a product or product [***] which falls within the [***] of [***] (each, an " **[***]** "), the [***] is obligated to deliver to the other Party a [***] at least [***] prior to the [***] of such [***] or [***] (the date on which such notice is given, the "[***]"), and the [***] Party shall have [***] following the [***], upon written notice to the [***] Party, to require [***] a [***] or [***] or [***] the [***] of [***] and [***] A failure to comply with this provision shall be considered a [***] of [***].

2.9 **No Additional Licenses** . Except as expressly provided in **Sections 2.1** , **2.2** , **2.3** , **2.5, 3.1(e)(vi)** and **Article 11** , nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of the other Party (either expressly, by implication or by estoppel).

2.10 **Bankruptcy** .

(a) All rights and licenses to Intellectual Property granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for the 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 a 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.

(b) Notwithstanding any other provision of this Agreement, for purposes of Section 365(n)(2)(B) of the Bankruptcy Code, "royalty payments" shall mean solely (i) those amounts payable in **Section 3.1(c), 3.1(d), and 3.1(e)** , in respect of Initial Products, (ii) any incremental royalty payments payable to Momenta in connection with an Opt-Out of Co-Funding with respect to the applicable Products, and (iii) any development milestones, sales milestones and royalties that may be negotiated and agreed pursuant to **Section 3.1(g)** in respect of [***] Products other than the [***] Product. Where, [***], [***] does not meet its [***] in respect of [***] shall automatically terminate and [***] and [***] in [***] shall be payable in respect of Products Commercialized and sold in the U.S.

ARTICLE 3.
FINANCIAL TERMS

3.1 **Consideration** .

(a) **Up-Front Payment** . Within thirty (30) days following the Effective Date, CSL shall make a non-creditable, non-refundable upfront payment to Momenta of Fifty Million Dollars ($50,000,000).

(b) **[***]** . Upon the achievement of the [***] in respect of the [***], CSL shall make a non-creditable, non-refundable payment to Momenta of [***] within [***] after such [***] is achieved; provided that if the [***] is not met but the [***] is [***] to [***] the [***] into [***], the [***] for the [***] shall be deemed to have been met, and CSL shall make the [***] payment to Momenta within [***] after [***]. For the avoidance of doubt, the payment pursuant to the provisions of this **Section 3.1(b)** is [***] is or [***] and shall not be affected by any [***] by [***] the [***] or [***].

(c) **Development Milestones** . For the [***] for the First Product, CSL shall make the below-listed Development milestone payments to Momenta, in each case within [***] after the achievement of the corresponding milestone event. For [***] for the [***], CSL shall make [***] of the below-listed

Development milestone payments to Momenta within [***] after the achievement of the corresponding milestone event in respect of the [***]. Each such Development milestone payment shall [***].

Development milestone events for the First Product	Milestone payment if Momenta is not Co-Funding	Milestone payment if Momenta is Co-Funding
1. [***]	[***]	[***]
2. [***]	[***]	[***]
3. [***]	[***]	[***]
4. [***]	[***]	[***]
5. [***]	[***]	[***]
6. [***]	[***]	[***]
7. [***]	[***]	[***]

Payment for Milestone [***] where [***] after [***] of [***]. In the case of both the First Product and the [***] Product, in the event that Momenta is [***] the [***] the [***] by such Product but Momenta [***] the [***] of [***] prior to [***] by such Product, the amount that would have been paid on [***] of [***] by such Product had [***] at [***] by such Product shall be paid on:

(i) the [***] of [***] by such Product if the [***] of [***] by such Product occurs after [***] to [***] such Product; or

(ii) the [***] of [***] by such Product if the [***] of [***] by such Product occurs [***] such Product.

Payment for Milestone [***] where [***] after [***] of [***]. In the case of both the First Product and the [***] Product, in the event that Momenta [***] the [***] the [***] by such Product but Momenta [***] the [***] of [***] prior to [***] of [***] by such Product, the amount that would have been paid on [***] of [***] by such Product had [***] at the [***] by such Product shall be paid on the [***] of [***] by such Product. For the avoidance of doubt, if Momenta [***] after the [***] by such Product, [***] shall be paid.

(d) **Sales Milestones** . CSL shall make the below-listed Annual Net Sales milestone payments to Momenta in respect of the Products, in each case, with respect to the [***] in which such Annual Net Sales milestones are achieved. For avoidance of doubt, the Annual Net Sales milestones set forth in the table below reflect the aggregate Annual Net Sales of all Products in any given calendar year. Each such Annual Net Sales milestone payment shall be [***]. CSL will notify Momenta in writing that an Annual Net Sales milestone has been achieved at the same time as it provides the royalty statement pursuant to **Section 3.3** for the Calendar Quarter in which such milestone was achieved and will then make the payment required in respect of such Annual Net Sales milestone together with the royalty payment for such Calendar Quarter. For the avoidance of doubt, if more than one Annual Net Sales Milestone payment is achieved in any year, all such milestones shall be payable for such year. Each such Annual Net Sales milestone payment shall be [***]. If in any year there are Net Sales of [***] or [***] Products that Momenta is [***] and [***] or [***] that [***] is [***] the [***] of [***] or [***] is [***] of [***] is [***] and [***] the [***] of [***] of [***] is [***] of [***] is [***].

Milestone Payments if Momenta is Not Co-Funding		**Milestone Payments if Momenta is Co-Funding**	
Global Annual Net Sales (in the aggregate) for all Products	**Milestone Payment**	**Annual Net Sales (in the aggregate) outside the United States for all Products**	**Milestone Payment**
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

(e) **Royalty Payments** . CSL shall pay to Momenta, during the Royalty Period, a royalty on Net Sales of each [***] (whether such sales are made by it, its Affiliates or Sublicensees) as follows:

(i)

Royalties if Momenta is Not Co-Funding		**Royalties if Momenta is Co-Funding**	
Global Annual Net Sales	**Royalty rate**	**Annual Net Sales outside the United States**	**Royalty rate**
The portion that is [***]	[***]	The portion that is [***]	[***]
The portion that is [***] and [***]	[***]	The portion that is [***] and [***]	[***]
The portion that is [***] and [***]	[***]	The portion that is [***] and [***]	[***]
The portion that is [***]	[***]	The portion that is [***]	[***]

(ii) For the avoidance of doubt, a royalty is payable on a country-by-country basis where such sales of [***] meet one of the following criteria:

(1) the sale or use of such [***] in [***] would infringe a granted Valid Claim of any Momenta Patent Right or any Joint Patent Right in that country where (i) the [***] is [***] of the [***] of [***] in the [***] in the [***] of [***] and (ii) for the purpose of determining whether such Valid Claim is infringed, no effect is given to any license granted under this Agreement or to any [***] of [***] to [***];

(2) [***] applies to the [***] in that country; or

(3) the sale is made in a country within the period of [***] from [***] of such [***] in that country.

(iii) If, during the Royalty Period for an [***], on a country-by-country basis:

(1) Neither **Section 3.1(e)(ii)(1)** nor **Section 3.1(e)(ii)(2)** applies to such [***]; and

(2) such [***] is [***] to [***] from a product [***] with respect to [***] and which has [***], then the Royalty payable by CSL in respect of such [***] in such country shall be [***] of the [***] described in **Section 3.1(e)(i)** .

(iv) If CSL pays [***] or [***] pursuant to a [***] or an [***] for a Product then the royalties payable to Momenta may be reduced as provided for in **Section 7.6** .

(v) If CSL is unable to fully offset under **Section 3.1(e)(iv)** above amounts paid to Third Parties pursuant to [***] and/or [***] against royalties due for a Calendar Quarter as permitted in accordance with **Section 7.6** , CSL shall be entitled to [***] to [***] for [***], subject to the limitations in **Section 7.6** .

(vi) Upon the expiration of the Royalty Period with respect to any Product in any particular country in the Territory, CSL shall have a [***] in such country to the Momenta Intellectual Property to research, Develop, make, use, import, sell, have made, have sold and otherwise Commercialize such Product.

(f) **Royalty set for convenience of the Parties.** Given the worldwide scope of this Agreement, the impracticality of monitoring by CSL of the movement of [***] Product(s) through international markets, that Momenta will, or may, be granted new patents from time to time in various countries throughout the Territory throughout the Term that will be licensed hereunder, and the impracticality of establishing the relative contribution of each Momenta Patent Rights and Momenta Know-How to the value of [***] Product(s), in particular at the stage in the Development cycle for the [***] Product(s) at which the Parties are entering into this Agreement, it is agreed and recognized that paying royalties on worldwide sales of [***] Product(s) at the rates set forth in this Agreement is fair and reasonable, representing a balance between the concerns and interests of both Parties and resulting in a convenience for CSL.

(g) **Financial Terms for [***] Products other than the [***] Product** . Subject to **Section 3.1(d)** and **Article 4** , if there is a decision to proceed with the Development of a [***] Product other than the [***] Product pursuant to **Section 5.1(d)** , the amount of milestones and the amount of royalties and which, if any, of Momenta Patent Rights, CSL Patent Rights and/or Joint Patent Rights should trigger any obligation to pay a royalty shall be [***] the [***] and [***] to [***] the [***] the [***] for such Product; provided that if a [***] the [***] the [***] to [***], then the Parties [***] the [***] in [***] and [***] the [***] is [***] to [***] the [***] the [***] to [***] the [***] to the [***] of the [***]. The [***] or [***] in the [***]. The [***] of [***] the [***] be [***] to [***].

3.2 **Invoices and payment** Unless expressly provided otherwise in this Agreement, following CSL's achievement of an event in respect of which a payment (other than a royalty or Annual Net Sales milestone payment) is due to Momenta under this Agreement, including Development milestones payments, CSL shall provide Momenta with written notice of such achievement [***] of such occurrence. Momenta shall then invoice CSL for the amount payable, which payment shall be payable within [***] of receipt by CSL of a duly rendered invoice from Momenta.

3.3 **Net Sales Statements** . CSL will accrue all Net Sales for the applicable Products and will maintain books and records in respect of same in accordance with the terms and conditions hereof and in accordance with applicable Accounting Standards. From the first Calendar Quarter in which the First Commercial Sale of Product is made and for so long as a royalty remains payable under this Agreement with respect to any Product, CSL will, within [***] after the end of each [***], submit to Momenta a [***] of the Net Sales during the just-ended [***]. Within [***] after the end of each Calendar Quarter, CSL will submit to Momenta a Net Sales Statement and accompany such statement with payment of the royalty.

3.4 **Program Expenses** . Subject to Momenta's obligations in connection with its Co-Funding Options in **Article 4** , from and after the Effective Date, CSL shall bear all Program Expenses. Except to the extent that provisions of **Article 4** apply as a result of Momenta's exercise of a Co-Funding Option, then within [***] of the end of each Calendar Quarter, Momenta shall provide CSL with an invoice for the Program Expenses incurred by Momenta during such Calendar Quarter and CSL shall reimburse Momenta for such Program Expenses within [***] of the receipt of such notice.

3.5 **Currency** . All payments under this Agreement will be made in United States Dollars. For the purpose of calculating payments made or costs incurred in currencies other than Dollars, each Party will apply an

exchange rate sourced from a reputable source, which it will notify to the other Party from time to time, in accordance with its then-standard internal practices, consistently applied.

3.6 **Payments to be made to the Parties' nominated bank accounts.** All payments due to be paid to a Party pursuant to this Agreement must be made to that Party's bank account notified to the payer in writing (which notification will include, for any given invoice, the necessary wire transfer instructions and relevant information). At the Execution Date:

Momenta's bank account details are:

[***]

Account Number: [***]

[***]

CSL's bank account details are:

[***]

Account Number: [***]

ARTICLE 4.
CO-FUNDING OPTIONS; REPORTING AND RECORD KEEPING

4.1 **In General** . CSL hereby grants to Momenta the following co-funding options in respect of the Products and the [***] Products; provided that Momenta may exercise only one of the following co-funding options:

(a) Momenta shall bear fifty percent (50%) of the global Research Expenses of the [***] Products, fifty percent (50%) of global Development Expenses for the Products and fifty percent (50%) of Commercialization Expenses and [***] in the United States for the Products, in each case from and after the Co-Funding Option Effective Date, in exchange for which Momenta shall receive fifty percent (50%) of all Profits and Losses for the Products and Research Products in the United States (the " **50% Co-Funding Option** ") and the applicable milestones and royalties as set forth in **Section 3.1** . Momenta may exercise its 50% Co-Funding Option by written notice to CSL [***] after the [***] for the [***].

(b) Momenta shall bear fifty percent (50%) of the global Research Expenses of the [***] Products, fifty percent (50%) of global Development Expenses for the Products and fifty percent (50%) of Commercialization Expenses and [***] in the United States for the Products, in each case from and after the Co-Funding Option Effective Date, in exchange for which Momenta shall receive thirty percent (30%) of all Profits and Losses for the Products and [***] Products in the United States (the " **30% Co-Funding Option** ") and the applicable milestones and royalties as set forth in **Section 3.1** . Momenta may exercise its 30% Co-Funding Option by written notice to CSL at any time prior to [***] after the date on which Momenta receives [***] the [***] of the [***] or [***], in each case in respect [***] the [***] is [***] and [***] to [***] (taking into account any [***] of any [***] with respect [***] may be made [***]).

4.2 **Opt-Out of Co-Funding** .

(a) Total Opt-Out . At any time on and after the Co-Funding Option Effective Date, Momenta has the right, in its sole discretion, to cease Co-Funding for all current and future Products upon [***] written notice to CSL (the " **Opt-Out Notice** "); provided that, following the effective date of such Opt-Out Notice:

(i) Momenta shall have no further obligation to co-fund Research, Development or Commercialization of any Product or [***] Product and shall have no right to share in the applicable Profit percentage; and

(ii) Momenta will be entitled to receive all royalty and milestone payments, for all Products, that are achieved following the Opt-Out Notice Effective Date. For the avoidance of doubt, Momenta will not be eligible to receive any payment under **Section 3.1(c)** for a Development Milestone achieved prior to the Opt-Out Notice Effective Date except to the extent expressly provided with respect to Milestones 1 and 2 in **Section 3.1(c)** ; and

(iii) CSL shall make [***] ([***] provided for below) to Momenta in a [***] to [***] (the [***]), [***] follows:

(1) all [***], excluding [***] or [***] the [***] for which it [***], [***] reference to the [***] and [***] and taking into account both [***] and [***] the [***] to the [***] following preparation of each such [***];

(2) [***] any [***] to Momenta as [***] of [***].

The [***] shall be [***] by way of [***] in the [***] of [***] up to a [***] of a [***] in such [***] on [***], in the form of such [***] the [***]. In addition, CSL shall [***] to [***] within [***] of the Opt-Out Notice Effective Date, [***] or [***] by [***] for which it has [***] any [***].

(b) Future Product Opt-Out . If Momenta is Co-Funding any Product at the time the [***] for a [***] is [***], Momenta has the right[***], upon giving written notice to CSL within [***] after the [***] for such [***] is [***], to opt out of Co-Funding that Product and all future Products and future [***] Products. In such event, Momenta would continue to [***] to the [***] to [***] under this section. [***] that were [***] or [***] for [***] which it will no longer be Co-Funding (that is, excluding those which were incurred in respect of [***] which Momenta is continuing to Co-Fund) shall be [***] the [***] of [***] in such [***] on [***] until Momenta [***], in the form of [***], the relevant [***].

4.3 **Cost Share and Profit Share for Co-Funding of Products and [***] Products** . If, and during the period for which, Momenta is Co-Funding, the Parties shall comply with the following financial reporting requirements:

(a) **Initial Payment of Program Expenses** . Except as expressly provided otherwise in this Agreement, the Party initially incurring Program Expenses will be responsible for and pay for all Program Expenses so incurred. Each Party will accrue all Program Expenses for [***] Products and Products and maintain books and records for same in accordance with the terms and conditions hereof and in accordance with applicable Accounting Standards. Within [***] after the end of each [***], each Party will submit to the other Party a non-binding, good faith estimate of such Program Expenses accrued and Net Sales, as applicable, during the just-ended [***].

(b) **Summary Statements.** Within [***] after the end of each Calendar Quarter, each Party will submit to the other Party a Summary Statement. Such Summary Statements shall:

(i) specify in reasonable detail all expenses included in such Program Expenses during such Calendar Quarter and, upon the reasonable request of the other Party, shall be accompanied by invoices, and/or other appropriate supporting documentation; or

(ii) report Program Expenses and Losses which are subject to Momenta's current Co-Funding on a [***] (*e.g.* , [***] costs and [***] costs); and

(iii) contain a separate summary of the Program Expenses and Losses which Momenta is required to share pursuant to its Co-Funding.

In order to accomplish this, the Parties shall seek to resolve any questions related to the non-binding, good faith estimate of such Program Expenses [***] and Net Sales provided pursuant to **section 4.3(a)** above, as applicable, within [***] following receipt by each Party of the other Party's estimate. Thereafter, the JSC shall facilitate the finalization of the Parties' Summary Statements, as applicable, hereunder and the resolution of any questions concerning such Summary Statements. Upon the request of either Party from time to time, the Parties' [***] personnel will discuss any reasonable questions or reasonably arising issues in relation to the Summary Statements, including the basis for the accrual of specific Program Expenses (provided that where such Program Expenses were [***] or [***] and are within the amount most recently budgeted for the relevant Activity, the [***] that any question or issue is [***] shall be on the Party [***] such question or issue).

(c) **Reimbursement and Co-Funding Report** . Within [***] after the last day of each Calendar Quarter, CSL will prepare a Reimbursement and Co-Funding Report. Without limiting the foregoing, the Reimbursement and Co-Funding Report for each such Product shall include:

(i) the [***] and [***] which are to be shared by the Parties pursuant to Momenta's Co-Funding (to be drawn from the Parties' respective Summary Statements and setting out details of [***] and [***] pursuant to **Section 4.3(b)** and [***]);

(ii) following the First Commercial Sale of any Product, the [***] sales of Product on a country-by-country and Product-by-Product basis, sold by each Party, its Affiliates and Sublicensees during the Calendar Quarter, including the amount of such Product sold and the [***] invoiced for such Product;

(iii) a calculation of Net Sales of such Product from [***], including [***] on [***] allowed to be taken pursuant to [***], along with a description of the [***], [***] and [***] for such [***]; and

(iv) The calculation, for the relevant period, of the US Profits (which, for the avoidance of doubt, the Parties agree could be [***]) and Losses, including [***] on the (A) [***] including [***], including [***] on [***] of [***], [***] and [***] variances, [***] reevaluations and [***] and any other applicable components, along with applicable accounting policies, methodologies and calculations for such components; (B) [***], including itemized information on applicable components of such costs, along with applicable accounting policies, methodologies and calculations for such components; (C) [***]; and (D) all [***] Program [***].

(d) **Payments of Cost Share and Profit Share.** Based on the Reimbursement and Co-Funding Report, the applicable Party (to whom a net amount is owed to achieve the applicable Profit and Loss share percentage as set forth in **Section 4.1**) will invoice the other Party after such Reimbursement and Co-Funding Reports are complete, and the receiving Party will pay such invoice within [***] of receipt of invoice.

4.4 **Semi-Annual Reports when Momenta not Co-Funding** . For Products which Momenta is not Co-Funding, CSL must deliver to Momenta, via the JSC, a [***] report (within [***] after [***] and [***]) that sets out, in summary form, the material elements of its Development and Commercialization plans for the preceding [***] and the [***] and shall include [***] or [***] of such plans which it [***] or [***] in the [***] and [***] or [***] of such plans which it did [***] or [***] including [***] for such [***] or [***], together with an [***] for any changes in related [***]. For the purpose of the semi-annual report provided under this Section, the Commercial plan summary shall contain the information provided under clauses (a)(iii), (iv), (v), (vi) and (viii) of **Section 1.32** .

4.5 **Overdue Payments** . If any payment owed to a Party under this Agreement is not made when due, such outstanding payment shall accrue interest (from the date such payment is due through and including the date upon which full payment is made) at a rate of [***] per month from the due date until paid in full; provided that in no event shall said annual rate exceed the maximum interest rate permitted by Applicable Law in regard to

such payments. Such payment, when made, shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate nor waive the right of a Party to any other remedy, legal or equitable, to which it is entitled because of the delinquency of the payment.

4.6 **Taxes.** The royalties and milestones payable under **Article 3** , and other amounts due to either Party hereunder (" ***Payments*** ") shall not be reduced by any value-added tax or any other sales tax or duties unless required by Applicable Law; provided , however , that the Parties shall cooperate to minimize any tax liability. Each Party alone shall be responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be paid by the other Party) levied on account of, or measured in whole or in part by reference to, any Payments it receives; provided , however , that the payer shall deduct or withhold any applicable withholding taxes or similar mandatory governmental charges levied by any governmental jurisdiction from the amount due to the other Party hereunder which the payer is required by Applicable Law to deduct or withhold. CSL and Momenta will cooperate in obtaining any necessary documentation required under applicable tax law, regulation, or intergovernmental agreement. Notwithstanding the foregoing, if the Party receiving the Payment is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to the payer or the appropriate governmental authority (with the assistance of the payer to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the payer of its obligation to withhold tax, and the payer shall apply the reduced rate of withholding, or dispense with withholding, as the case may be, provided that the payer has received evidence, in a form reasonably satisfactory to it, of the other Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] prior to the time that the Payments are due. If, in accordance with the foregoing, the payer withholds any amount, it shall pay to the other Party the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to the other Party proof of such payment within [***] following that payment. Without limiting the generality of the foregoing, the Parties acknowledge and agree that: (i) [***] is [***] and [***] is [***]; (ii) under current [***] and [***], no amount contemplated to be payable under this Agreement by [***] is subject to any [***] or [***]; and (iii) [***] a [***] in [***], [***] from the amounts payable pursuant under this Agreement [***] in respect of [***], provided that Momenta delivers a properly [***] and duly [***].

4.7 **Audits; Records and Inspection** . CSL shall keep, and where Momenta has exercised a Co-Funding Option or a Co-Promotion Option or Momenta is performing Activities under a Research Plan or Product Work Plan, Momenta shall keep with respect to all relevant Products and [***] Products, complete, true and accurate books of account and records for the purpose of determining, as applicable, any reimbursement or the sharing of Program Expenses, Profits and Losses, and any royalty payable under this Agreement. Each Party shall also require its Affiliates and Sublicensees to keep all such books and records. Such books and records shall be kept at the principal place of business of each Party or its Affiliates or authorized Sublicensees, for at least [***] following the end of the Calendar Quarter to which they pertain. Upon [***] prior written notice from a Party, the other Party shall permit, and shall ensure that its Affiliates and Sublicensees shall permit, an independent certified public accounting firm of recognized international standing, selected by the requesting Party and reasonably acceptable to the other Party, at the requesting Party's expense, to have access to such Party's (or its Affiliates' or Sublicensees') records, specific to a country in the Territory, as may be reasonably necessary to verify the accuracy of any amounts reported, actually paid or payable under this Agreement for [***] to the date of such request. Such audits may be made no more than once each calendar year, during normal business hours at reasonable times mutually agreed by the Parties. If such accounting firm concludes that additional amounts were owed to the requesting Party during such period with respect to such country, or if the requesting Party overpaid for any rates or fees for products or services with respect to such country, the other Party shall pay such additional amounts or refund such overpayment (including interest on such additional sums with respect to such country of the Territory in accordance with **Section 4.5**) within [***] after the date the requesting Party delivers to the other Party such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by the requesting Party; provided , however , that if the audit discloses that the amounts payable to such Party for the audited period are more than [***] of the amounts actually paid for such period in such country of the Territory as applicable, or if the audit discloses that the other Party has [***] the [***] or [***] or [***] in the period in such country of the Territory as applicable, [***] then the other Party shall pay the reasonable fees and expenses charged by such accounting firm. Upon the

expiration of [***] the end of any calendar year, the calculation of any amounts payable with respect to such calendar year, or rates or fees charged for such year shall be binding and conclusive upon the Parties.

ARTICLE 5.
RESEARCH, DEVELOPMENT, MANUFACTURING AND COMMERCIALIZATION

5.1 **Research Collaboration.**

(a) **[***] Products** . During the Term or a part thereof, the Parties will undertake research in respect of [***], which may include the [***] Product, in accordance with the Research Plan, which will be discussed and [***] by the Parties, and reviewed [***] by the JSC no less frequently than [***]. Selection of each [***] to be included as a [***] Product in the Research Plan shall be subject to the [***] the [***]. In selecting [***] for inclusion in the Research Plan, the Parties will have regard to [***] and [***] and [***] obtained in respect of such [***] and shall bear in mind the best interests of the collaboration and their mutual desire to Develop and Commercialize Products.

(b) The initial Research Plan, including its duration and the [***] to be included as [***] Products, will be [***] by the Parties [***] of the Effective Date.

(c) The Research Plan, as in effect at any time, shall identify, at a minimum:

(i) the [***] to be subject to Research as [***] Products under the Research Plan;

(ii) the Research Activities to be conducted by each Party with respect to such [***] Products, including which Party will be responsible for the manufacture of [***] Products;

(iii) the estimated budget for such Research Activities on a [***] Product by [***] Product basis; and

(iv) any preliminary research that a Party may conduct at its own expense to facilitate the proposal of future Research Activities.

(d) [***] **Product Development and Commercialization Decision for** [***] **Products** . [***], at any time, [***], and shall so notify [***] and the notice provisions of this Agreement upon making such [***]. The date of such notice shall be the " **Development Approval Date** " for such [***] Product. ***From and after the Development Approval Date for such*** [***] ***Product, such*** [***] ***Product shall be deemed to be a "Product" under this Agreement*** .

5.2 **Development of Products**

CSL shall be responsible for Development of Products and for the [***] and [***] of Development Plans.

(a) Development of each Product, including the First Product and any [***] Product which becomes a Product under this Agreement as provided in **Section 5.1(d),** shall be conducted pursuant to a Development Plan.

(b) CSL shall prepare an initial Development Plan for the First Product on a basis consistent with the outline attached as **Schedule 5.2(b)** . [***] in the [***] the [***] and [***] to [***]. Such initial Development Plan shall be [***] by the JSC on or before [***] after the Effective Date, or at such other time that is mutually agreed in writing by the Parties.

(i) Momenta shall, unless otherwise provided for in the initial Development Plan for the First Product, use Commercially Reasonable Efforts to exercise Momenta's rights under its [***] and [***], at [***], to [***] of the First Product for the [***] for the First Product. The expenses of [***] such [***] incurred on and from [***] shall be included in the Development Plan and [***] in accordance with the provisions of this Agreement [***] of [***] they were incurred [***] of the Development Plan, and provided that they are [***] with [***] and [***] by email or correspondence.

(ii) The initial Development Plan and the initial Research Plan shall similarly provide for the [***] of [***] after the Effective Date regardless of whether such [***] to [***] the [***] or the [***] and provided that they are [***] with [***] and [***] by email or correspondence.

(c) CSL shall prepare an initial Development Plan for each [***] Product that becomes a Product under this Agreement. [***] in the [***] and [***] to [***]. Such initial Development Plan for such Product shall be [***] the JSC on or before [***] after the Development Approval Date for such [***] Product.

(d) During the [***] and [***] of any initial Development Plan, the Parties, through the JSC, shall [***] the following (subject to [***]): (1) [***] for the [***] of [***] for clinical development and potential [***], (2) [***] for [***] of clinical program [***], and (3) research efforts to [***] and [***] CSL agrees [***] to [***] related to (1), (2) and (3), which may involve activities to be performed at Momenta, including [***] for the [***] of [***].

(e) Each Development Plan shall be updated [***] and shall contain a [***] covering at least the [***], with [***] estimates for [***] to [***] along with a [***] of [***] and [***] and [***] expected to be [***] the [***] and [***] of development, in all cases consistent with [***] and [***] processes [***]. Without limiting CSL's general obligation to [***] as provided for in [***], [***] may [***] and [***] the Development Plan after [***] of the [***] Development Plan. [***] shall [***] through JSC meetings, Activity Reports and Annual Program Reviews provided for in **Sections 5.7, 5.8** and **Article 4** . [***] will [***] of [***] or [***] to the Development Plan and [***] the [***] with [***] CSL will provide an [***] to Momenta via the JSC at least each [***].

(f) As provided in [***] and [***]; CSL's [***], if [***] cannot [***] on the [***] of any initial Development Plan for any Product within the timeframe specified above, the Parties shall [***] the [***] to [***] in accordance with [***]. If the matter remains unresolved [***] after [***] to [***], the matter may be resolved by [***] in [***] to the [***] of [***].

(g) If Momenta is Co-Funding and CSL elects to take a [***] Product into Development and [***] the [***] and/or Commercialized are a [***] the [***] to [***] for such Product such that [***] with respect to such initial Development Plan, Momenta shall have the right to [***] such Product. Momenta shall [***] by written notice to CSL within [***] of [***]. Upon such notice, Momenta will be [***] to have [***] of [***] such Product and [***] (i.e., [***] of [***] or [***]), on the same basis and with the same consequences with respect to such Products (but no other Products) as provided with respect to all Products in **[***]**

5.3 **Commercialization of Products**

CSL shall be [***] and for the [***] and [***] of Commercialization Plans.

(a) Commercialization of each Product shall be conducted pursuant to a Commercialization Plan.

(b) CSL shall be [***] a Commercialization Plan for each Product.

(c) CSL shall [***] Commercialization Plan for each Product no later than [***] the first [***] seeking [***] for such Product in a Major Country.

(d) CSL shall [***], through [***], regarding the initial Commercialization Plan for any Product, but [***] the [***] by the JSC shall [***].

(e) CSL [***] may [***] and [***] the Commercialization Plan for any Product [***], and will provide an [***] Commercialization Plan to Momenta via the JSC at least each [***].

(f) The Commercialization Plan for each Product shall include [***] of [***] that is [***] to [***] Commercialization of such Product and [***] and [***].

5.4 **CSL's Obligation to Share Commercialization Plans** . CSL shall provide Commercialization Plans to the JSC [***] of [***] which Momenta [***], on a [***] basis, for [***] Momenta is [***] such Product.

5.5 **Manufacture of Products**

(a) CSL shall have the sole responsibility for Manufacturing strategy and shall be [***] all Products, including [***] and [***] of any [***].

(b) Notwithstanding the foregoing, Momenta will use Commercially Reasonable Efforts to assist with [***] from [***] to CSL and Momenta [***] that it has no knowledge, at the Execution Date, of any contractual or commercial objection, either of Momenta or of its [***] to [***].

5.6 **Responsibility; Diligence** .

(a) Subject to the terms of this Agreement, each Party and its Affiliates shall use Commercially Reasonable Efforts to undertake the Activities assigned to it under each Product Work Plan and the Research Plan.

(b) CSL shall use Commercially Reasonable Efforts to Develop, Manufacture and Commercialize Products in the Territory. Notwithstanding any other provision of this **Section 5.6** , CSL shall be deemed to have satisfied this obligation if CSL is [***] to (i) [***] for [***] for human use in [***] and (ii) to Commercialize each Product for human use [***] in which [***] is achieved.

(c) The Parties recognize and agree that commercial or scientific circumstances may mean that it [***] to continue Research, Development or Commercialization of a specific Product or [***] Product, and that [***] in such circumstances [***] a [***] to satisfy its [***] hereunder provided that [***] to use Commercially Reasonable Efforts to Research, Develop or Commercialize [***] or [***] for human use or [***] for human use in satisfaction of [***].

(d) CSL shall promptly notify Momenta of [***] of [***] on any Product or Research Product by means of a written report setting out in reasonably informative detail the reasons for [***] to [***], as applicable, Research, Development or Commercialization of such Product or [***] Product.

5.7 **Activity Reports** . Each Party shall report on Activities undertaken by it in accordance with and in performance of the Product Work Plans and the Research Plan. Such reports shall be provided in connection with meetings of the JSC or as otherwise required under this Agreement.

5.8 **Annual Program Review** . At the request of either Party, the JSC shall conduct an overall program review once each calendar year during the Term.

5.9 **Regulatory Matters**

(a) From and after the Effective Date, on a country-by-country basis, [***] for seeking Regulatory Approvals for the Products in each country in the Territory, in accordance with Product Work Plans. All Regulatory Submissions will be filed, [***] the [***] of [***] or its nominee, which entity will be the holder of all resulting Regulatory Approvals.

(b) CSL will keep the JSC [***] regarding the [***] relating to the [***] or [***] of any Regulatory Approval in the Territory, which include, but are not limited to, [***] and [***] of Regulatory Submissions, [***] and [***] and [***] with Regulatory Authorities.

(c) CSL agrees to [***] and to [***] in relation to [***] likely to be relevant to the Development and Commercialization of Products, including but not limited to [***], and further agrees that, [***] the Parties will, through the JSC, [***] and [***] and [***] from time to time.

5.10 **Momenta's Co-Promotion Option** .

(a) **In General** . Subject to [***] CSL hereby grants to Momenta an option, on the terms and subject to the conditions of this Agreement, to participate in the promotion, in the U.S., of those Products which it is Co-Funding.

(b) **Exercise** . Momenta may exercise its Co-Promotion Option with respect to a Product by written notice to CSL [***] prior to the [***] of the [***] for such Product as determined by reference to the most recent Development Plan for that Product reviewed by the JSC. On Momenta's request, CSL [***] the [***] be [***] and shall [***] to [***]. Momenta shall exercise its Co-Promotion Option by written notice to CSL, following which the Parties will [***] and [***], by [***] to [***] of the [***] (as determined by reference to the most recent Development Plan for that Product reviewed by the JSC) the Commercialization Activities which Momenta will undertake (determined taking into account [***] and [***] to [***] the [***]) and the terms of a Co-Promotion Agreement to govern such Activities and the parties' rights and obligations with respect thereto. The terms of such Co-Promotion Agreement shall be [***] and [***]. If the Parties cannot agree, the Parties shall [***] the [***] in [***], and [***] in [***] and [***] in [***] is [***]. If any inconsistency arises between the terms of this Agreement and the terms of the applicable Co-Promotion Agreement, the terms of this Agreement shall prevail. Momenta shall not have the right to promote any Product, unless and until a Co-Promotion Agreement, which permits the promotion by Momenta of such Product in the United States, is entered into by the Parties.

(c) **Co-Funding not affected by Co-Promotion.** The Parties shall continue to share Profits and Losses in accordance with **Article 4** with respect to each Co-Funded Product, regardless of whether Momenta exercises or does not exercise its Co-Promotion Option with respect to the Products.

(d) **CSL to book all sales.** CSL will book (directly itself or indirectly through any of its Affiliates and Sublicensees) all sales revenue of the Products in the Territory.

(e) **Consequences for Co-Promotion of decision by Momenta not to exercise its Co-Funding Option or of Co-Funding Opt-Out** . Momenta's rights under this **Section 5.10** will cease as of:

(i) the deadline for Momenta's exercise of its 30% Co-Funding Option, if Momenta fails to exercise its Co-Funding Option; or

(ii) the Opt-Out Effective Date for each Product in respect of which Momenta has exercised, or still maintains, a Co-Funding Option and subsequently exercises its right to opt out of such Co-Funding Option,

and any Co-Promotion Agreement shall automatically terminate in accordance with its terms.

5.11 **Exclusive Collaboration** . For as long as there is [***], each Party shall collaborate exclusively with respect to any [***] with the other Party regarding Research or Development and shall not, and shall ensure that its respective Affiliates and Sublicensees shall not, independently undertake, or collaborate with or license any Third Party or any [***] who has Intellectual Property and activities [***] the [***] the [***] of [***] to [***] and/or Development of any [***] without the other Party`s prior written consent (which may be granted or withheld in such other Party's absolute discretion). During the Term each Party shall collaborate exclusively with respect to any [***] with the other Party regarding Manufacture or Commercialization and shall not, and shall ensure that its respective Affiliates and Sublicensees shall not independently undertake, or collaborate with or license any Third Party or any [***] who has Intellectual Property and activities [***] the [***] the [***] of [***] to [***] or [***] of any [***] without the other Party's prior written consent (which may be granted or withheld in such other Party's absolute discretion). Exceptions from these obligations apply as follows:

(a) To perform such [***] as may be required to [***] and [***] a [***] for [***] as a [***] Product under this Agreement as provided in **Section 5.1** (Research Collaboration);

(b) To conduct [***] or [***] with respect to an Acquired Product in compliance with **Section 2.8** ; and

(c) As provided in **Section 5.12** ([***]) and **Section 5.14** ([***] on the [***] in Certain Circumstances).

The provisions of this **Section 5.11** shall not apply to any activity by an [***] of a Party following a [***] or any Affiliate of such [***] (other than an Affiliate of such Party prior to the [***]) to the extent that such activity is engaged in without using or incorporating any Collaboration Technology Controlled by such Party or otherwise licensed to such Party under this Agreement, where [***] or [***] the [***] or [***] of [***] or [***] of [***] of [***].

5.12 **[***]** . In respect of any Product [***] is [***] or [***], or any [***] to [***], CSL will reasonably consider and discuss [***] of [***] and/or [***] such Product or [***] Product. Momenta may initiate discussions regarding such [***] at any time by written notice to CSL. Following such discussion, CSL will notify Momenta [***] to [***] and [***], such [***] to [***], and [***] of its [***]. In no circumstances shall it be [***] to [***] to any [***] and/or [***] of a Product or [***] Product in [***] which is included in [***] or [***]. For the avoidance of doubt, the provisions of this Section do not [***].

5.13 **Development or Commercialization other than for Human Use.** Neither Party will be required to Co-Fund or invest any amounts in respect of activities (including Activities) aimed at exploitation, Development or Commercialization of Products or [***] other than for human use unless it has provided prior written consent to such activities. Should [***] to initiate Development or Commercialization of a [***] in a field other than for human use, [***] and [***] and [***] of a [***]. The Parties shall [***] and [***] to [***] on such terms within [***] of [***] the [***]. If after [***], the Parties are [***], then the Parties shall resolve the dispute first through [***], and if the [***] are unable to resolve the dispute, the Parties will try, in [***], to resolve the dispute by [***] pursuant to the [***] of the [***]). The [***] or [***] the [***]. The place of [***] will be [***]. If the dispute cannot be resolved by [***] within [***], such dispute will be resolved by [***].

5.14 **Further Research on the First Product by Momenta in Certain Circumstances.** Where the [***] is [***], and CSL has not [***] after the [***] the [***], of [***] either to [***] the [***] Clinical Trial or of [***] to [***] to [***] the [***] (which the Parties agree could [***] prior to [***] or [***]), Momenta may [***] with respect to the [***] with a view to [***] and [***] the [***]. Following such [***], Momenta may present the [***] to CSL [***] and if, following [***] of [***], CSL [***] of the [***], Momenta's [***] the [***] into the [***] shall be considered [***] under this Agreement .

ARTICLE 6.
GOVERNANCE

6.1 **In General** . The Parties will establish a JSC. The structure, scope of responsibility and authority of the JSC shall be as set forth in this **Article 6** and are subject to the terms of this Agreement.

6.2 **Structure** . The JSC shall initially consist of four (4) representatives from each of CSL and Momenta, including each Party's Alliance Manager. The JSC shall appoint a chairperson from among its members, who shall be a representative from CSL. The chairperson shall be responsible for notifying the Parties' representatives of JSC meetings and for leading the meetings. The initial JSC representatives for each Party shall be set forth in writing within [***] after the Effective Date. Each Party may replace its representatives by providing written notice to the other Party. Employees and other representatives of each Party who are not members of the JSC may attend meetings of the JSC and any Sub-Committees as requested by that Party's members of the JSC.

6.3 **Time and Location of Meetings** . The JSC (and all Sub-Committees thereof) shall meet at such times and in such manner (either in person or remotely) as the JSC shall determine; provided , however , that the initial meeting of the JSC shall be held no later than [***] after the Effective Date. Thereafter, the JSC shall meet at least once per [***] and in any event within [***] of receiving [***] which requires [***] the [***] and either a [***] the [***] or [***], the timing of which [***] on the JSC meeting. [***] of [***] meetings of the JSC, determined on an annual basis, shall be held in the [***] or [***].

6.4 **Minutes** . The JSC and all Sub-Committees thereof shall designate for each meeting one (1) person who shall be responsible for drafting and issuing minutes of the meeting reflecting all material items discussed and any agreements of the JSC, which minutes shall be distributed to all JSC members for review and approval. Such minutes shall provide a description in reasonable detail of the discussions held at the meeting and a list of any actions, or determinations arising out of the meeting. Minutes of each JSC meeting shall be distributed to all JSC members [***] of such meeting and shall be finalized and approved [***] after each such meeting. Approval of minutes may be indicated by email and by signature by one (1) JSC member from each Party; provided that if a Party's JSC members have not notified the JSC of such members' disapproval of such minutes prior to [***] after the meeting, such minutes shall be deemed approved by, and binding on, such Party's JSC members. Final minutes of each meeting shall be distributed to the members of the JSC by the chairperson.

6.5 **Sub-Committees** . The JSC may agree upon the formation of certain Sub-Committees to assist it to discharge its functions under this Agreement. Sub-Committees shall not have decision-making authority and may only provide advice, guidance and recommendations to the JSC, or provide oversight of particular activities undertaken by the Parties pursuant to the Agreement and report back to the JSC to enable it to perform its [***] and [***] functions.

6.6 **Scope of Authority; Responsibilities** .

(a) The JSC shall perform the functions and assume the responsibilities and have such authority only as set forth in this Agreement. The JSC shall perform [***] and [***], including reviewing and providing input on the [***] and [***] and [***] the [***] performed under the Product Work Plans and the Research Plan and facilitating the sharing of information and reporting of [***] between the Parties.

(b) For the avoidance of doubt, the JSC shall have no authority to: (i) amend any of the terms of this Agreement, including by means of JSC minutes, Product Work Plans, Research Plans or otherwise; (ii) waive any rights that either Party may otherwise have pursuant to this Agreement or otherwise; (iii) allocate the ownership of any Patent Rights or rights to any Know-How or the Parties' rights to apply for Patent(s); or (iv) interpret this Agreement, or determine whether or not a Party has met its diligence or other obligations under the Agreement or whether or not a breach of this Agreement has occurred. Notwithstanding the foregoing, the JSC may make recommendations to the Parties for amendment of this Agreement.

6.7 **Review and approval by JSC; CSL's Final Decision-Making Authority.** If a provision of this Agreement requires the approval of the JSC, such approval must be unanimous, with representatives of CSL having one (1) collective vote and representatives of Momenta having one (1) collective vote; provided that if the JSC fails to reach such approval, the Parties shall refer the dispute to their respective senior management representatives in accordance with **Section 13.11(a)** . If the matter remains unresolved [***] referral to such senior management representatives, the matter may be resolved [***].

6.8 **Concerns regarding costs of Activities in respect of Products which Momenta is Co-Funding.** If Momenta is Co-Funding a Product (a " ***Co-Funded Product*** ") and the actual Program Expenses of Development and/or Commercialization of such Co-Funded Product exceed the budgeted amounts for such Co-Funded Product by more than [***] over [***] and the [***] for [***] for the [***] also [***] the [***] in the [***] by more than [***], and such [***] does [***] to [***] to [***] in [***] or [***] by [***], in each case in relation to the relevant Co-Funded Product then the following process shall apply:

(a) At least thirty (30) days prior to the next scheduled meeting of the JSC, Momenta may notify CSL in writing [***] in [***] detail [***] of [***] in [***] to the [***] with [***] to [***]. The matter will then be discussed at the next meeting of the JSC, at which meeting CSL [***] a [***] of [***] in [***] to [***], including any [***] its [***] and [***].

(b) If Momenta is [***] that CSL's [***] its [***], Momenta may, [***] the [***] each [***] for resolution under [***].

(c) If Momenta's [***] after [***] to [***], Momenta may [***] the [***] for [***] as [***] in [***], and then [***] in [***] for [***] in [***] with [***] to determine whether [***] and, if so, [***] the [***] by [***] in [***] of the [***] a [***] in [***] to [***] the [***]. The [***] shall have at least [***] has [***] the [***] or [***] of a [***] or [***]. In determining whether [***] were [***] of [***], the [***] shall have regard to the Activities set out in the current and previous Product Work Plans for such Co-Funded Product, any changes in the scope of such Activities [***] were [***] or [***] by [***] for the [***] or [***] of the relevant Product, the [***] for such [***], any [***] to the [***] of [***] which [***] the [***] of [***] be [***] to the [***] of [***] that [***] to [***] on [***] the [***]. If, following [***], it is determined that [***] are [***] and the [***] by [***] were [***] of [***] by [***] shall be [***] for [***] by the [***] to be [***] of [***] and [***] to [***] of [***] by [***] after such [***].

6.9 **Costs and Expenses of JSC** . Each Party shall be responsible for all travel costs, labor costs and out-of-pocket expenses incurred by its respective representatives in connection with attending the meetings and otherwise being part of the JSC and of any Sub-Committee.

6.10 **Term of the JSC and Sub-Committees** . The JSC shall, unless otherwise mutually agreed by the Parties, continue through the Term.

6.11 **Alliance Managers** .

(a) **Appointment** . Each of the Parties shall appoint an Alliance Manager. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party.

(b) **Responsibilities** . The Alliance Managers shall be appointed members of the JSC and each Sub-Committee and shall attend all JSC and Sub-Committee meetings and support the chairpersons of JSC and Sub-Committees in the discharge of their responsibilities. In addition to the Alliance Managers' duties as members of the JSC, each Alliance Manager: (i) will be the point of first referral in all matters of conflict resolution; (ii) will identify and bring disputes to the attention of the JSC in a timely manner; and (iii) will take responsibility for ensuring that governance activities, such as the conduct of required JSC and Sub-Committee meetings and production of meeting minutes, occur as set forth in this Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

ARTICLE 7.
INTELLECTUAL PROPERTY

7.1 **Ownership** . The following ownership arrangements will apply unless the Parties [***] in and agree to varying them in respect of any particular Intellectual Property.

(a) **Ownership of Intellectual Property** . Determinations as to which Party owns any Patent Right or Know-How developed pursuant to this Agreement will be made in accordance with the standards of inventorship under [***]. Subject to the license grants under **Article 2** , as between the Parties (i) CSL or its Affiliates will own all Intellectual Property invented solely by or on behalf of CSL, and (ii) Momenta will own all Intellectual Property invented solely by or on behalf of Momenta. Each Party or its designated Affiliate, will own an undivided one-half interest in and to the Joint Intellectual Property. In the event inventorship and ownership of any Intellectual Property cannot be resolved by the Parties with advice of their respective intellectual property counsel, such dispute will be resolved through [***] to [***] at [***] in [***] and [***] and [***] and [***] or [***]. Each Party shall make such assignments as are required to effect the ownership allocations set forth in this **Section 7.1(a)** . Subject to the licenses granted to the other Party under this Agreement and the other terms of this Agreement, each Party has a right to exploit its interest in the Joint Intellectual Property without the consent of and without accounting to the other Party; provided that , neither Party may assign its right, title, or interest in the Joint Intellectual Property to any Person, except (a) in connection with a permitted transaction under **Section 13.3** , or (b) to an Affiliate; and further provided that , neither Party may [***] or [***] in [***] that [***] and [***] to a [***] or [***] in [***] with [***]. For avoidance of doubt, assertion of Momenta Patent Rights that are infringed by a third party with respect to a product that is not a [***] Product or a Product [***] is outside the scope of this Agreement.

(b) **Employee Assignment** . Each Party shall procure from each of its employees and permitted assignees and subcontractors who are conducting work under this Agreement, rights to any and all Intellectual Property such that it is properly secured as CSL Intellectual Property, Momenta Intellectual Property, and Joint Intellectual Property, as applicable, such that each Party shall receive from the other Party, without payments beyond those contemplated by this Agreement, the rights granted to such Party to use such CSL Intellectual Property (in the case of CSL), Momenta Intellectual Property (in the case of Momenta), Joint Intellectual Property, as applicable, pursuant to this Agreement. In the event such rights have not been secured or any original holder challenges such procurement, the Party responsible for procuring such rights shall bear the entire costs or damages arising from the failure of or challenge to such procurement.

7.2 **Prosecution and Maintenance of Patent Rights** .

(a) **Patent Prosecution and Maintenance** .

(i) Momenta will have the first right, but not the obligation, to prepare, file, prosecute and maintain the Momenta Patent Rights at Momenta's cost. Where Momenta Patent Rights Cover or, if issued would Cover, a Product or a [***] Product, Momenta will provide CSL with (i) [***] of, and a [***] to [***] the [***] any [***] or other [***] from which [***] the [***] can [***] and [***] and [***] with [***] the [***] to any [***] and will [***] in [***] and [***] such [***] and (ii) subject to **Section 7.9** , [***] or [***] or [***] which [***] to the [***] and [***] the Momenta Patent Rights, which correspondence or other communications or actions that are to be made during the course of an action before a national patent office in the Territory (*i.e.* , the United States Patent & Trademark Office) or national court in the Territory [***] the [***] of [***].

(ii) CSL will have the first right, but not the obligation, to prepare, file, prosecute and maintain the CSL Patent Rights in the Territory at CSL's cost. In respect of CSL Patents which arise out of the Research Plan or Product Work Plan, and only during the period in which Momenta retains a Co-Funding Option or is Co-Funding, CSL will provide Momenta with (i) [***] of, and a [***] to [***] the [***] any [***] or other [***] from which [***] the [***] can [***] and [***] and [***] with [***] the [***] to any [***] and will [***] in [***] and [***] such [***]; and (ii) subject to **Section 7.9** , [***] or [***] or [***] which [***] to the [***] and [***] the CSL Patent Rights, which correspondence or other communications or actions that are to be made during the course of an action

before a national patent office in the Territory (*i.e.* , the United States Patent & Trademark Office) or national court in the Territory [***] the [***] of [***].

(iii) On a case by case basis, the Parties will discuss, for a period not to [***], and agree which of them is best placed to prepare, file, prosecute and maintain the Joint Patent Rights in the Territory. Absent agreement, the Party which contributed the Product or [***] Product in the context of which the invention claimed in the Joint Patent Rights was invented or, if that [***] the [***] which [***] the [***] or [***] the [***] will [***] the [***] the [***] to manage such Patent Rights. The Party responsible for the prosecution of Joint Patent Rights shall bear the external costs of such Joint Patent Rights, and each Party shall be responsible for its own internal costs. The responsible Party shall provide the other Party with (i) [***] of, and a [***] to [***] the [***] any [***] or other [***] from which [***] the [***] can [***] and [***] and [***] with [***] the [***] to any [***], and will [***] in [***] and [***] such [***]; and (ii) subject to **Section 7.9** , [***] or [***] or [***] which [***] to the [***] and [***] the Joint Patent Rights, which correspondence or other communications or actions that are to be made during the course of an action before a national patent office in the Territory (*i.e.* , the United States Patent & Trademark Office) or national court in the Territory [***] the [***] of [***].

(iv) A Party providing comments in accordance with this **Section 7.2(a)** will provide such comments, if any, expeditiously and in any event in reasonably sufficient time to meet any filing deadline communicated to it by the other Party. The Party receiving any such patent application and correspondence will maintain such information in confidence, except for patent applications that have been published and official correspondence that is publicly available.

(b) **Second Rights** . If a Party decides not to file, prosecute or maintain a Patent Right pursuant to this **Section 7.2(a)** , to the extent such Patent Right Covers the Development, Manufacture or Commercialization of a Product or a [***] Product, such Party will give the other Party reasonable notice to that effect sufficiently in advance of any deadline for any filing with respect to such Patent Right to permit the other Party to carry out such activity. After such notice, such other Party may, subject to the terms of any applicable license, file, prosecute and maintain the Patent Right, and perform such acts as may be reasonably necessary for such other Party to file, prosecute or maintain such Patent Right at its own cost. If a Party does elect to file, prosecute and maintain a Patent Right pursuant to this **Section 7.2(b)** , then the non-electing Party shall provide such cooperation to the electing Party, including the execution and filing of appropriate instruments, as may reasonably be requested to facilitate the transition of such patent activities.

(c) **Patent Term Extensions** .

(i) Regardless of which Party is filing, prosecuting and maintaining any Patent Right pursuant to this **Article 7** , the Parties shall discuss all opportunities for patent term extensions with respect to the Momenta Patent Rights, the CSL Patent Rights and the Joint Patent Rights in the Territory, and seek to reach agreement on which Patent Rights to seek to extend.

(ii) Unless otherwise agreed under clause (i) above, in any country where only a single patent can be extended for a given Product, [***] the [***] to [***] to [***] that [***] for [***] in [***] or [***] that [***] for [***] in [***] for [***] for [***] and shall cooperate with [***] to allow [***] to [***] for [***] at [***].

(iii) The Parties will cooperate with each other including without limitation to provide necessary information and assistance as the other Party may reasonably request in obtaining patent term extension (including any supplemental protection certificates or the like) or any similar rights in any country in the Territory.

(iv) Except as provided in **Section 7.2(c)(ii)** above, CSL shall be responsible for the cost of seeking any extensions.

(d) **CREATE Act** . Notwithstanding anything to the contrary in this **Article 7** , the Parties have agreed to elect under the Cooperative Research and Technology Enhancement Act of 2004, (Public Law 108-453, 118 Stat. 3596 (2004)), as codified in 35 U.S.C. § 103(c)(2)-(c)(3) or 35 U.S.C. § 102(c), as applicable,

with respect to their rights under this **Article 7** . The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. § 100(h).

7.3 **Trademarks and Domain Names** .

(a) Each Party and its Affiliates shall retain all right, title and interest in and to its and their respective corporate names and logos.

(b) All Products are to be Commercialized in the Territory under the Product Trademark and the Product Domain Names. CSL will own all Product Trademarks and Product Domain Names, and is responsible for the filing, prosecution, registration and maintenance of such Product Trademarks and the registration and maintenance of such Product Domain Names. The expenses of the selection, filing, prosecution and maintenance of the Product Trademarks and obtaining and maintaining the Product Domain Name shall be borne by CSL.

(c) In the event either Party becomes aware of any actual or threatened infringement of any Product Trademark or Product Domain Name by a Third Party, such Party shall promptly notify the other Party and the Parties shall consult with each other and jointly determine the best way to prevent such infringement, including, without limitation, by the institution of legal proceedings against such Third Party. CSL shall have the first right to initiate, to control and to resolve (including by way of settlement) any such legal proceedings.

7.4 **Enforcement and Defense of Enforcement Intellectual Property** .

(a) **Notice of Infringement by a Third Party** . Each Party shall provide to the other Party prompt written notice of any Infringement of the subset of Patent Rights and Know-How Controlled by a Party (x) to the extent such Patent Rights or Know How are exclusively owned by, are Joint Intellectual Property or exclusive license rights are held by, a Party or the Parties with respect to the relevant Product or for the class of [***], other than under a license under this Agreement; and (y) to the extent such claims are directed to inventions Covering the manufacture, sale, import or use of a Product or a [***] Product (the " **Enforcement Intellectual Property Rights** "), in all cases prior to initiating any legal proceedings with respect to such Infringement.

(b) **Initial Right to Enforce** . Subject to **Section 7.4(d)** and the provisions of any Third Party License, and solely with respect to the Enforcement Intellectual Property Rights, (i) [***] the [***] to [***] a [***] or take other appropriate action that it believes is reasonably required to protect (i.e., prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce (x) CSL Intellectual Property and Joint Intellectual Property in the Territory and (y) any [***] to [***] where the alleged Infringement involves manufacture or sale, or threatened manufacture or sale, of a product that is, or will, compete with a Product under this Agreement and (ii) [***] the [***] to [***] a [***] or take other appropriate action that it believes is reasonably required to protect (i.e., prevent or abate actual or threatened infringement or misappropriation of) or otherwise enforce [***] in the Territory except as set out in (i). The other Party shall have the right to participate in such suit or action as provided for in **Section 7.4(d)** .

(c) **Step-In Right** . Subject to the provisions of any Third Party License, and solely with respect to the Enforcement Intellectual Property Rights, if the Party with the first right to enforce (the " **Initial Enforcement Rights Party** ") Momenta Intellectual Property, CSL Intellectual Property or Joint Intellectual Property fails to initiate a suit or take other appropriate action that it has the initial right to initiate or take pursuant to **Section 7.4(b)** with respect to an Infringement within ninety (90) days after becoming aware of the basis for such suit or action, then the other Party (the " **Secondary Enforcement Rights Party** ") may, in its discretion, provide the Initial Enforcement Rights Party with written notice of such Secondary Enforcement Rights Party's intent to initiate a suit and control or take other appropriate action with respect to such Infringement in the Territory. If the Secondary Enforcement Rights Party provides such notice and the Initial Enforcement Rights Party fails to initiate a suit or take such other

appropriate action within thirty (30) days after receipt of such notice from the Secondary Enforcement Rights Party, then the Secondary Enforcement Rights Party shall have the right to initiate a suit and to control or take other appropriate action that it believes is reasonably required to protect Momenta Intellectual Property, CSL Intellectual Property or Joint Intellectual Property, as applicable, from such Infringement in the Territory.

(d) **Participation; Conduct of Certain Actions; Costs** . The Party initiating suit shall have the sole and exclusive right to select counsel for any suit initiated by it pursuant to **Section 7.4(b)** or **Section 7.4(c)** and to control such suit or other action; provided that:

(i) The other Party shall have the right to participate, and upon request, review pleadings and discuss strategy with the Party initiating suit, including discussions with [***] counsel. The other Party shall have the right to be represented in any such suit that is based on an Infringement by its own counsel at its own expense;

(ii) The initiating Party shall be solely responsible for the costs associated with the posting of security for any injunctions, without the prior written consent of the other Party, which absent such consent shall not constitute Commercial Expenses under this Agreement and shall be reimbursed from any recoveries under **Section 7.4(e)** ; and

(iii) The initiating Party shall not resolve or settle any action taken pursuant to this **Section 7.4** where such settlement would affect the other Party's entitlement to receive payments under this Agreement or the validity of the other Party's Intellectual Property Rights without the prior written consent of the other Party which shall not be unreasonably withheld or delayed.

(iv) If required under applicable law in order for the initiating Party to initiate and/or maintain such suit, the other Party shall join as a party to the suit. Such other Party shall offer reasonable assistance to the initiating Party in connection therewith at no charge to the initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred in rendering such assistance. The initiating Party shall assume and pay all of its own out-of-pocket costs incurred in connection with any litigation or proceedings initiated by it pursuant to **Section 7.4(b)** or **Section 7.4(c)** , including without limitation the fees and expenses of the counsel selected by it.

(e) **Costs Reimbursement and Recoveries** . The out-of-pocket costs paid by a Party in connection any litigation or proceedings initiated under this **Section 7.4** shall be reimbursed to such Party by the proceeds of any awards, judgments or settlements obtained in connection with an Infringement in the Territory, and the remainder of such proceeds shall be treated as Net Sales for the purpose of determining royalties or Profit share under this Agreement.

7.5 **Third Party Claims and Suits** .

In the event that a Party becomes aware of any claim that the research of any [***] Product or the Development, Manufacture or Commercialization of any Product infringes or misappropriates the Intellectual Property rights of any Third Party, such Party shall promptly notify the other Party. In any such instance the [***] of [***] or [***] the [***] the [***] the [***] to [***] and to [***] of [***]. Expenses of such litigation shall be deemed to be [***] the [***] and [***] the [***]. If the [***] of [***], the [***] shall have the right to [***], to be [***] by its [***], at its [***], or where feasible [***] with the [***]. Each Party shall provide to the other Party copies of any notices it receives from Third Parties regarding any such alleged infringement or misappropriation or the agreed upon course of action. Such notices shall be provided promptly, but in no event after more than [***] following receipt thereof.

7.6 **Third Party Licenses** .

(a) Where a Party, its Affiliates or its Sublicensees identifies the need or is otherwise offered a license, covenant not to sue or similar rights to Third Party Intellectual Property that are (i) [***] to

[***] or [***] of such Third Party Intellectual Property based on the Research of a Research Product or the Development, Manufacture or Commercialization of a Product or (ii) [***] the Research of a [***] Product or the Development, Manufacture or Commercialization of a Product, [***] to [***] or [***] with [***] to [***] or [***], such Party shall promptly notify the other Party. The Parties shall thereafter [***], regarding whether such Third Party Intellectual Property is [***] the Research of a [***] Product or the Development, Manufacturing and Commercialization of a Product. Subject to the provisions in this **Section 7.6** , CSL [***] to [***] in [***] of such Third Party Intellectual Property or any other Third Party Intellectual Property which it [***] to [***] the Development and/or Commercialization of Products. The Parties agree to allocate the risk and opportunity associated with such future licenses entered into with Third Parties (" **Third Party Licenses** ") as provided for herein.

(b) [***]: In the event such Third Party License is [***] (but not [***] or [***]) any Intellectual Property [***] Momenta to CSL under this Agreement (a "[***]"), CSL, its Affiliates or Sublicensees [***] the [***] to [***] the [***] of [***]. In such event, then:

(i) When Momenta is Co-Funding the Product, (1) the royalties payable on sales of such Product in any country under such [***] and (2) any licensee fees and milestone payments [***] to or [***] and [***] to the [***] in the calculation of Research Expenses, Costs of Goods Sold and/or Manufacturing Expenses, as provided for in the definition of such expenses;

(ii) When Momenta is not Co-Funding the Product (1) the royalties payable on sales of such Product in any country under such [***] and (2) any licensee fees and milestone payments solely attributable to or [***] to [***], and [***] to the [***] to [***] to the [***] to [***] up to [***] of the amount of such license fees, milestones or royalties paid to such Third Party under any such [***] License; provided that such reduction [***] in any given [***] in the Royalty Term;

(c) [***]: In the event CSL, any of its Affiliates or Sublicensees enters into a [***] that CSL determines is [***] for the Development and Commercialization of a Product ("[***]"), then the Parties agree that the following provisions will apply unless the Parties specifically agree, in writing, to the contrary:

(i) When Momenta is Co-Funding the Product, (1) the royalties payable on sales of such Product in any country under such [***] and (2) any licensee fees and milestone payments [***] to or [***] to [***], and [***] to the [***] shall be included in the calculation of [***], as provided for in the [***] of [***];

(ii) When Momenta is not Co-Funding the Product (1) the royalties payable on sales of such Product under such Approved Third Party License and (2) any licensee fees and milestone payments [***] to or [***] to [***] and [***] to the [***] shall be [***] to Momenta for such Product under Section 3.1(e) [***] to the [***] to [***] to the [***] the [***] or [***] to such Third Party under any such [***]; provided that [***] shall [***] the [***] in any Calendar Quarter by more than [***] (e.g., no more than a reduction from [***] of the then-applicable royalty rate.

For this purpose of this Section, "[***]" shall mean the percentage calculated by dividing (X) the [***] in a Calendar Quarter before any deduction in respect of such Approved Third Party License by (Y) which shall be calculated by [***] (1) [***] to [***] in a Calendar Quarter before any [***] in [***] of [***] (2) [***] in [***] of [***].

(d) Other Third Party Licenses: Subject always to the obligations of **Section 7.6(a),** each Party is free to enter into any Third Party Licenses that do not impose obligations on the other Party, and the Parties may elect to discuss and seek to agree to alternative allocation of Third Party License arrangements in lieu of the provisions provided for in subsections (b) and (c) of this **Section 7.6** .

7.7 **Patent Marking** . Each Party agrees to mark or virtually mark and have its Affiliates and all Sublicensees mark or virtually mark all Products (or their containers or labels) sold pursuant to this Agreement in accordance with the applicable statutes or regulations in the country or countries of manufacture and sale thereof.

7.8 **Biosimilar or Interchangeable Biological Product Patent Exchange** . If the Party that is the reference product sponsor of a Product within the meaning of § 351(l)(1)(A) of the PHS Act receives notice of a Biosimilar Application filed by a § 351(k) applicant that references such Product and related manufacturing information in accordance with § 351(l)(2)(A) of the PHS Act or receives a notice of commercial marketing in accordance with § 351(l)(8)(A) of the PHS Act, then such Party will provide notice to the other Party, and the Parties will discuss and cooperate with each other in determining such Party's course of action with regard to (a) engaging in the information exchange provisions of the BPCIA, including providing a list of patents that relate to the relevant Product, (b) engaging in the patent resolution provisions of the BPCIA, and (c) determining which patents will be the subject of immediate patent infringement action under § 351(l)(6) of the BPCIA. In the event that the Parties do not agree with respect to the exercise of any such rights, [***] with [***] the [***] with [***] with [***] and [***]. If any patent litigation commences with respect to a Biosimilar Application filed by a § 351(k) applicant that references such Product, then the provisions of **Section 7.4** will thereafter apply as if such § 351(k) applicant were an infringer or suspected infringer.

7.9 **Privileged Communications** . In furtherance of this Agreement, it is expected that Momenta and CSL will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they will remain confidential, they will not be deemed to waive any applicable attorney-client privilege and that they are made in connection with the shared community of legal interests existing between CSL and Momenta, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of CSL Patent Rights, Momenta Patent Rights and Joint Patent Rights.

ARTICLE 8.
CONFIDENTIAL INFORMATION

8.1 **Confidentiality** . Except as contemplated by this Agreement, each Party shall hold in confidence and shall not publish or otherwise disclose and shall not use for any purpose (except for the purposes of carrying out its obligations or exercising its rights under this Agreement): (a) any Confidential Information of the other Party disclosed to it pursuant to the terms of this Agreement, (b) the terms of this Agreement (subject to **Section 8.4**) until [***] after the expiration or termination of this Agreement. The members of the JSC and any Sub-Committees shall use pricing and other competitive commercial information provided by the other Party solely for purposes contemplated by this Agreement and shall not share such information more broadly within their organizations. All Confidential Information of a Party, including all copies and derivations thereof, is and shall remain the sole and exclusive property of the disclosing Party and subject to the restrictions provided for herein. Subject to **Sections 8.2, 8.3, 8.4** and **8.5** , neither Party shall disclose any Confidential Information of the other Party other than to those of its directors, officers, Affiliates, employees, actual or potential licensors, independent contractors, actual or potential licensees or Sublicensees (if permitted), actual or potential investors, lenders, assignees, agents, and external advisors directly involved in or concerned with the carrying out of this Agreement, on a strictly applied "need to know" basis; provided , however , that such persons and entities are subject to confidentiality and non-use obligations at least as stringent as the confidentiality and non-use obligations provided for in this **Article 8** .

8.2 **Public Disclosure** . The Parties have attached hereto as **Exhibit 8.2** , a mutually acceptable press release announcing this Agreement (the " **Initial Press Release** "). The JSC shall review, from time to time, proposed disclosures of the Parties relating specifically to this Agreement (or related activities, results or events) and consent for such disclosures shall not be unreasonably withheld, delayed or conditioned. Except: (a) as determined by a Party to be reasonably necessary to comply with Applicable Law (including applicable securities laws and the rules and regulations of exchanges upon which a Party's securities are traded); (b) with respect to JSC approved disclosures; and (c) with respect to the Initial Press Release as agreed upon between the Parties, neither Party shall issue a press release or make any other public disclosure of the terms of this Agreement or the progress of Research, Development or Commercialization of any Product, [***] Product or [***] without the prior approval of such press release or

public disclosure by the other Party. Each Party shall submit any such press release or public disclosure to the other Party, and the receiving Party shall have [***] from receipt to review and approve any such press release or public disclosure, which approval shall not be unreasonably withheld, delayed or conditioned, and provided that should the requesting Party request earlier review, the receiving Party shall use reasonable efforts to respond within a shorter timeframe. If the receiving Party does not respond to the other Party within such [***] period, the press release or public disclosure shall be deemed approved. Notwithstanding the preceding requirements related to a press release or other public disclosure, if a public disclosure is required by Applicable Law, including without limitation in a filing with the Securities and Exchange Commission or any securities exchange on which such Party's securities are traded, the disclosing Party shall provide copies of the disclosure reasonably in advance of such filing or other disclosure for the non-disclosing Party's prior review and comment. The first approval of the contents of a press release or public disclosure shall constitute permission to use such contents subsequently without submission of the press release or public disclosure to the other Party for approval.

8.3 **Legally Required Disclosures** . If the receiving Party or any of its representatives is required by law, rule or regulation or by order of a court of law, administrative agency, or other governmental body or any securities exchange on which such Party's securities are traded, to disclose any of the Confidential Information, the receiving Party will (a) promptly, and if practicable, provide the disclosing Party with reasonable advance written notice to enable the disclosing Party the opportunity to seek, where appropriate, a protective order or to otherwise prevent or limit such legally required disclosure, (b) use reasonable efforts to cooperate with the disclosing Party to obtain such protection, and (c) disclose only the legally required portion of the Confidential Information. Any such legally required disclosure will not relieve the receiving Party from its obligations under this Agreement to otherwise limit the disclosure and use of such information as Confidential Information.

8.4 **Confidential Terms** . Except as expressly provided herein, each Party agrees not to disclose any terms of this Agreement to any Third Party without the consent of the other Party; provided , however , that disclosures may be made on a strict need to know basis to actual or prospective investors, acquirers, financing sources or licensees, or to a Party's accountants, attorneys and other professional advisors; provided, further, that such persons and entities are subject to confidentiality and non-use obligations at least as stringent as the confidentiality and non-use obligations provided for in this **Article 8** .

8.5 **Prior Agreements** . All Confidential Information (as that term is defined in the Prior Confidentiality Agreement and the Prior Material Transfer Agreement) disclosed pursuant to the Prior Confidentiality Agreement or the Prior Material Transfer Agreement, respectively, shall be considered Confidential Information under this Agreement, subject to the exceptions in **Section 1.36** .

8.6 **Return of Confidential Information** . Each Party shall return or destroy, at the other Party's instruction, all Confidential Information of the other Party in its possession upon termination or expiration of this Agreement, The receiving Party shall provide a written confirmation of such destruction within thirty (30) days after such destruction; provided that the foregoing shall not apply to any Confidential Information that is legally required to be retained (including by any Regulatory Authority) or necessary to allow such Party to perform its obligations or exercise any of its rights that expressly survive the termination or expiration of this Agreement.

ARTICLE 9.
INDEMNIFICATION AND LIMITATION OF LIABILITY

9.1 **CSL Indemnification** . CSL agrees to defend Momenta and its Affiliates, and their respective agents, directors, officers and employees (the " **Momenta Indemnitees** "), at CSL's cost and expense, and will indemnify and hold harmless the Momenta Indemnitees from and against any and all [***] a [***] or [***] or [***] that [***] (collectively, " **Momenta Losses** ") arising out of any act or omission of CSL, its Affiliates, Sublicensees, contractors or agents in connection with the development, use, manufacture, distribution or sale of a Product, including, but not limited to, any actual or alleged injury, damage, death or other consequence occurring to any Person claimed to result, directly or indirectly, from the possession, use or consumption of, or treatment with, a Product, whether claimed by reason of breach of warranty, negligence, product defect or otherwise, and regardless of the form in which any such claim is made; provided that the foregoing indemnity shall not apply to the extent

that any such Momenta Losses are attributable to: (a) Momenta's breach of this Agreement, including any warranty; or (b) Momenta's or any Momenta Indemnitee's, Momenta subcontractor's or Momenta Sublicensee's failure adequately to perform its designated Activities pursuant to any applicable Product Work Plan; or (c) Momenta's or any Momenta Indemnitee's, Momenta subcontractor's or Momenta Sublicensee's performance of any action or activity not designated to it under this Agreement or any applicable Product Work Plan; or (d) the negligence, gross negligence or willful misconduct of Momenta, the Momenta Indemnitees or of any Momenta subcontractor or Momenta Sublicensee. If any such claim against any Momenta Indemnitee arises, Momenta shall promptly notify CSL in writing of the claim and CSL shall manage and control, at its sole expense, the defense of the claim and its settlement. Notwithstanding the foregoing, no settlements shall be finalized without obtaining Momenta's prior written consent, which shall not be unreasonably withheld, delayed or conditioned, except that in the case of a settlement that does not require an admission or action on the part of Momenta, and does not harm Momenta or its ability to comply with its obligations hereunder, Momenta's consent shall not be required so long as Momenta is unconditionally released from all liability in such settlement. Momenta shall cooperate with CSL and may, at its discretion and expense, be represented in any such action or proceeding. CSL shall not be liable for any settlements, litigation costs or expenses incurred by Momenta Indemnitees without CSL's written authorization.

9.2 **Momenta Indemnification** . Momenta agrees to defend CSL and its Affiliates, and their respective agents, directors, officers and employees (the " **CSL Indemnitees** "), at Momenta's cost and expense, and will indemnify and hold harmless the CSL Indemnitees from and against any and [***] on [***] or [***] or [***] that [***], (collectively, " **CSL Losses** ") arising out of any act or omission of Momenta, its Affiliates, Sublicensees, contractors or agents in connection with the development, use, manufacture, distribution or sale of a Product, including, but not limited to, any actual or alleged injury, damage, death or other consequence occurring to any Person claimed to result, directly or indirectly, from the possession, use or consumption of, or treatment with, a Product, whether claimed by reason of breach of warranty, negligence, product defect or otherwise, and regardless of the form in which any such claim is made; provided that the foregoing indemnity shall not apply to the extent that any such CSL Losses are attributable to: (a) CSL's breach of this Agreement; or (b) CSL's, or any CSL Indemnitee's, CSL's subcontractor's or CSL's Sublicensee's failure adequately to perform its designated Activities pursuant to any applicable Product Work Plan; or (c) CSL's or any or any CSL Indemnitee's, CSL's subcontractor's or CSL's Sublicensee's performance of any action or activity not designated to it under this Agreement or any applicable Product Work Plan; or (d) the negligence, gross negligence or willful misconduct of CSL, the CSL Indemnitees or of any CSL subcontractor or CSL Sublicensee. If any such claim against any CSL Indemnitee arises, CSL shall promptly notify Momenta in writing of the claim, and Momenta shall manage and control, at its sole expense, the defense of the claim and its settlement. Notwithstanding the foregoing, no settlements shall be finalized without obtaining CSL's prior written consent, which shall not be unreasonably withheld, delayed or conditioned, except that in the case of a settlement that does not require an admission or action on the part of CSL, and does not harm CSL or its ability to comply with its obligations hereunder, CSL's consent shall not be required so long as CSL is unconditionally released from all liability in such settlement. CSL shall cooperate with Momenta and may, at its discretion and expense, be represented in any such action or proceeding. Momenta shall not be liable for any settlements, litigation costs or expenses incurred by CSL Indemnitees without Momenta's written authorization.

9.3 **Joint Loss Liability** . To the extent that any Third Party product liability related losses, costs, liabilities, damages, fees or expenses remain unallocated to an Indemnifying Party under **Sections 9.1 and 9.2** , after following the procedures for such indemnification thereof and any dispute arising in connection with such claims for indemnification, such unallocated Third Party product liability related losses, costs, liabilities, damages, fees or expenses [***] to [***].

9.4 **Insurance** .

(a) Each Party shall maintain insurance or self-insurance (including a captive insurance company), including product liability insurance, with respect to its activities under this Agreement. Such insurance or self-insurance shall be in such amounts and subject to such deductibles as are prevailing in the industry from time to time, provided that , each Party and its Affiliates and Sublicensees shall maintain a minimum of an aggregate of (a) [***] in general comprehensive liability insurance, (b) [***] in product liability

insurance [***] of [***], and (c) [***] in product liability insurance no later than [***] following [***] of [***].

(b) Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than [***] or [***] and [***] is greater than [***]

9.5 **No Consequential Damages** . UNLESS RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR FROM A PARTY'S BREACH OF **ARTICLE 2** OR **ARTICLE 8,** NO PARTY WILL BE LIABLE TO THE 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 9.5** IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER THIS AGREEMENT.

ARTICLE 10.
EXPORT

10.1 **General** . The Parties acknowledge that the exportation from the United States of materials, products and related technical data (and the re-export from elsewhere of items of U.S. origin) may be subject to compliance with U.S. export laws, including without limitation the U.S. Bureau of Export Administration's Export Administration Regulations, the Federal Food, Drug and Cosmetic Act and regulations of the FDA issued thereunder, and the U.S. Department of State's International Traffic and Arms Regulations, which restrict export, re-export, and release of materials, products and their related technical data, and the direct products of such technical data. The Parties agree to comply with all export laws and to commit no act that, directly or indirectly, would violate any U.S. law, regulation, or treaty, or any other international treaty or agreement, relating to the export, re-export, or release of any materials, products or their related technical data to which the U.S. adheres or with which the U.S. complies.

10.2 **Delays** . The Parties acknowledge that they are not responsible for any delays attributable to export controls that are beyond the reasonable control of either Party.

10.3 **Assistance** . The Parties agree to provide assistance to one another in connection with each Party's efforts to fulfill its obligations under this **Article 10** .

10.4 **Other** . The Parties agree not to export, re-export, or release any item that may be used in the design, development, production, stockpiling or use of chemical or biological weapons in or by a country listed in Country Group D: 3 of Part 370 to Title 15 of the U.S. Code of Federal Regulations as it may be updated from time to time.

ARTICLE 11.
TERM AND TERMINATION

11.1 **Term** . This Agreement shall be binding upon the Parties as of the Effective Date. The term of this Agreement (the " **Term** ") shall commence on the Execution Date, and, unless earlier terminated as provided in this **Article 11** , shall continue in full force and effect until the later of:

(a) the expiration of all payment obligations with respect to Products; and

(b) if Momenta exercises a Co-Funding Option, the [***] of [***] to [***] or [***] on [***] it [***] ceases to Co-Fund any Product; and

(c) the date on which there are no active Product Work Plans.

11.2 **Termination by CSL** :

(a) Prior to achievement of [***] . CSL may terminate the Agreement in its [***] or [***] to the [***] at any time prior to the date on which the [***] would become payable for the [***], by giving [***] to Momenta ([***] period between the notice and the Termination Date, the [***]); provided that CSL shall be obligated to pay to Momenta the [***] as set forth in [***] within [***] of giving Momenta such termination notice regardless of whether such [***] is [***]

(b) After Failure to Achieve [***] . If the [***] with respect to the [***] is not met, CSL may terminate the Agreement [***] or [***] to the [***] by giving [***] Momenta within [***] after the [***] with respect to the [***] is not achieved.

(c) Termination Prior to [***] . CSL may, by giving not less than (x) [***] if a Product does not achieve [***] in [***] in the Development Plan, or (y) [***] written notice otherwise, to Momenta, terminate the Agreement:

(i) [***] or [***] to the [***] (A) at any time after the [***] is [***] but before the [***] of the [***], or (B) more than [***] after the [***] with respect to the [***] is not achieved but before the [***] of the [***] or

(ii) with respect to a Product other than [***], at any time before the [***] of [***].

(d) Termination After [***] . CSL may terminate the Agreement in its entirety or with respect to a Product at any time after the [***] in [***] to Momenta.

11.3 **Termination by Momenta.** If CSL elects to terminate the Agreement with respect to the [***], then Momenta may terminate the Agreement [***] by providing written notice to CSL [***] of the [***] of the [***], with such termination becoming effective the date on which [***].

11.4 **Termination for [***]** . Either Party may terminate this Agreement on a Product-by-Product basis and on a [***] Product-by-[***] Product basis, on not less than [***] written notice to the other Party if the non-terminating Party or its Affiliates (directly or indirectly, [***] or in [***] with any other [***]) [***] the [***] or [***] of any [***] the [***] of [***] or [***] of [***] of such Product or [***] Product (if the terminating Party is CSL) or [***] the [***] or [***] of such Product or [***] Product (if the terminating Party is Momenta) or any of the [***] the [***] or [***] of such Product or [***] Product, provided however that, subject to the termination rights set out herein, each Party acknowledges and agrees that nothing in this clause [***] the [***] or [***] any of the [***] referred to in this **Section 11.4** and provided further that:

(a) CSL shall not have the right to terminate this Agreement [***] or [***]:

(i) [***] a [***] that is [***] the [***] or [***] to [***] under this Agreement, in an [***], such as a [***], or other [***] or [***] in a good faith effort to [***] within such [***]; or

(ii) [***] a [***] that is [***] the [***] or [***] to [***] under this Agreement [***] a [***] in [***] by [***] of such [***].

(b) Momenta shall not have the right to terminate this Agreement [***] or [***]:

(i) [***] a [***] that is [***] the [***] in an [***], such as a [***], or other [***] or [***] in a good faith effort to [***] within such [***]; or

(ii) [***] a [***] that is [***] the [***] a [***] in [***] by [***] of [***]

11.5 **Termination for Material Breach.**

(a) Subject to **Section 11.5(b)** , a Party may terminate this Agreement entirely or with respect to a Product upon written notice specifying a date of immediate or future effectiveness if the other Party has materially breached this Agreement (provided that, if such material breach relates only to a Product, then the Party's right to terminate is limited to such Product), and such breach is not cured by that Party [***] of [***] of such breach and the non-breaching Party's intent to terminate; provided that if such breach is not susceptible of cure within such period and the Party in breach uses diligent good faith efforts to cure such breach, the stated period will be extended by an additional [***].

(b) If an alleged material breach pertains to a failure to exercise Commercially Reasonable Efforts, the following process will apply:

(i) If a Party believes that the other Party is not exercising Commercially Reasonable Efforts with respect to a Product or as otherwise required under this Agreement, that Party (the " **Alleging Party** ") may notify the other Party (the " **Alleged Breaching Party** ") in writing as to what [***] for the [***] to [***] its obligations to exercise such Commercially Reasonable Efforts, taking into account any [***] undertaken by the Alleged Breaching Party to date in relation to such obligations. Within [***] of receipt of such notice, the Alleged Breaching Party must either:

(1) inform the Alleging Party that it agrees that such expectations are reasonable, in which case it will also provide a [***] that [***] the [***] the [***] to [***]; or

(2) provide the Alleging Party with a detailed written explanation as to why the Alleged Breaching Party is [***] to [***] and [***] the [***].

(ii) If the Alleging Party is satisfied that the [***] under [***] the allegations, notwithstanding any other provisions of this Agreement to the contrary, the Alleged Breaching Party [***] and [***] to [***] the [***] a [***]. If the Alleged Breaching Party fails to take such steps in a timely manner, the Alleging Party may [***] the [***] or [***] the [***] by [***] (provided that, if the [***] to [***] relates only to a Product, the Alleging Party's right to terminate is limited to such Product).

(iii) If the Alleging Party is [***] that the [***] provided under **Section 11.5(b)(i)(1)** resolves the allegations, or if the Alleged Breaching Party provides notice under **Section 11.5(b)(i)(2)** , the Alleging Party may, acting reasonably, [***] the [***] to [***] the [***] and, if necessary, [***] in [***] with [***] to determine whether the [***] has [***] its [***] to use Commercially Reasonable Efforts and/or whether any [***] provided under [***], if implemented, would [***] any [***] to [***] such [***].

(iv) If the matter is referred to [***] and following such [***]:

(1) it is determined that the Alleged Breaching Party has [***] its [***] to exercise [***], no [***] shall be taken with respect to such [***];

(2) it is determined that the Alleged Breaching Party has [***] its [***] to exercise such [***] and the [***] provided under [***] (if any) [***] the [***], the [***] shall take [***] and [***] to [***] the [***] in a timely manner; provided however that if the Alleged Breaching Party [***] to [***] such [***] in a timely manner, the [***] may terminate the Agreement entirely or with respect to the relevant Product by immediate written notice (provided that, if the failure to exercise Commercially Reasonable Efforts relates to a Product, the Alleging Party's right to terminate is limited to that Product);

(3) it is determined that the Alleged Breaching Party has [***] its [***] to exercise [***] and either [***] was provided under [***], or the [***] provided under that [***] does [***] the [***], the Alleging Party may terminate the Agreement entirely or with respect to the relevant Product by immediate written

notice (provided that, if the failure to exercise Commercially Reasonable Efforts relates to a Product, the Alleging Party's right to terminate is limited to that Product).

11.6 **Termination for Bankruptcy** . To the extent permitted under Applicable Law, either Party may terminate this Agreement immediately upon written notice to the other Party, if, at any time: (a) the other Party files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of substantially all of its assets; (b) the other Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within [***] after the filing thereof; (c) the other Party shall propose or be a party to any dissolution or liquidation; or (d) the other Party shall make an assignment of substantially all of its assets for the benefit of creditors. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code.

11.7 **Consequences of Termination** . Consequences of Termination are described with respect to three categories of termination: (1) where Momenta has the right to the return of the Product(s), and (2) where CSL has the right to continue and retain the Product(s), and (3) where the Agreement is terminated [***] the [***].

(a) **Termination Where Momenta Has the Right to the Return of the Product(s)** . Without limiting any other legal or equitable remedies that either Party may have, if this Agreement or a Product under the Agreement is terminated:

- by CSL under [***] for [***] other than where the [***] is [***] in its [***] by CSL [***],
- by Momenta under [***] for [***],
- by Momenta for [***] under [***],
- by Momenta for [***] or [***] under [***], or
- by Momenta for [***] under [***],

the following provisions will take effect as of the Termination Date (or upon the giving of a termination notice where indicated) with respect to the Product(s) for which the Agreement has been terminated:

(i) CSL will use Commercially Reasonable Efforts to promptly transfer to Momenta or its designee: (A) possession and ownership of all governmental and regulatory correspondence, conversation logs, filings and approvals (including all Regulatory Approvals) [***] or [***] that [***] and [***] related to the Development, Manufacture or Commercialization of the terminated Product(s); (B) copies of all data, reports, records and materials [***] or [***] and [***] to the Development, Manufacture or Commercialization of the terminated Product(s), including all [***] and [***] relating to the terminated Product(s); (C) all inventory of terminated Product(s) [***]; and (D) all records and materials [***] or [***] containing Confidential Information of Momenta relating [***] to the [***] provided , however , that CSL shall be entitled to retain one copy of all such Confidential Information for purposes of determining its obligations under this Agreement. Effective as of the date of the termination notice, CSL will, [***], and [***] and [***] cooperate with Momenta, either to transition all Development activities initiated prior to the Termination Date with respect to the terminated Products and wind down, transition, and end such Development activities in an orderly manner;

(ii) CSL will, [***] in [***]: (A) [***] Momenta as CSL's and/or its Affiliates' [***] for all terminated Product-related matters involving Regulatory Authorities; or (B) appoint a mutually [***] to [***] as a [***] for [***] on [***] behalf for the period of time after termination necessary to allow for an [***] of the regulatory file or Regulatory Approval. Momenta agrees to use [***] to the [***] the [***];

(iii) If, at the time of termination, CSL is performing process development or Manufacturing activities for the terminated Product(s), CSL shall upon [***] and [***] to [***] to [***] and [***]

associated therewith, [***] to effect a transfer of such activities to Momenta or a Third Party nominated by Momenta. If Momenta so requests, CSL will assign to Momenta any agreements with Third Parties reasonably necessary for and primarily relating to the Development, Manufacture or Commercialization of the terminated Product(s) to which CSL is a party to the extent permitted by the terms of such agreements; provided , however , that CSL [***] to [***] or to [***]. In addition, effective upon the giving of a notice of termination, (A) CSL shall meet with Momenta to immediately discuss and plan transfer and transition activities; (B) CSL shall use Commercially Reasonable Efforts to manufacture Products [***] the [***] of [***] that [***] to [***] to [***] to [***] or [***] of [***] is [***]; and (C) CSL shall use Commercially Reasonable Efforts to cooperate with Momenta in initiating the post-Termination transition activities provided for in this **Section 11.7(a)** ;

(iv) the licenses granted to CSL and Momenta pursuant to **Article 2** (other than the licenses granted under **Section 2.3** with respect to Joint Intellectual Property) will terminate with respect to the terminated Product(s) (or entirely if the whole Agreement is terminated) (except to the extent necessary to enable CSL to perform its obligations under this **Section 11.7** with respect to the terminated Products **)** ; provided , however , that CSL shall grant Momenta a [***] license under CSL Intellectual Property and CSL's interest in the Joint Intellectual Property existing as of the Termination Date to make, have made, use, develop, import, offer for sale, sell and have sold the terminated Product(s). Where Momenta does not have control or hold the first right to enforce Momenta Patent Rights or Joint Patent Rights under **Section 7.4** or to defend litigation brought against Momenta under **Section 7.5** , CSL shall transfer control of such litigation to Momenta and CSL shall assume the rights and obligations previously held by Momenta in such litigation proceedings.

(v) Momenta shall pay to CSL:

(1) a royalty of [***] on Net Sales of the terminated Product(s) until [***] of [***] incurred with respect to such Product through the Termination Date are reimbursed, provided, however, that if such termination occurs with respect to [***] to [***] to [***] or [***] to [***] the [***] the only royalty payable shall be the royalty specified in [***]; and

(2) commencing only after the royalty payable pursuant to **Section 11.7(a)(v)(1)** is no longer payable, a royalty of [***] of each terminated Product that, but, for the licenses granted hereunder, would infringe a Valid Claim in a CSL Patent Right or a Joint Patent Right existing as of the Termination Date;

(vi) Until the expiry of Momenta's obligation to pay royalties under **Section 11.7(a)(v)** , Momenta shall provide CSL with Quarterly reports of Net Sales in relation to the terminated Product(s) in a level of detail equivalent to that required in respect of Net Sales Statements;

(vii) CSL will assign to Momenta all right, title and interest in the Product Trademarks and Product Domain Names for the terminated Product(s) and [***] Product(s) and all goodwill associated therewith;

(viii) Subject to any surviving licenses granted to the other Party under this Agreement (including the license to Momenta in **Section 11.7(a)(iv)**) and any other terms of this Agreement that survive termination, each Party may exploit its interest in the Joint Intellectual Property without the consent of and without accounting to the other Party;

(ix) CSL shall submit payment to Momenta for any amounts paid by Momenta related to Commercialization Expenses incurred through the Termination Date for which CSL is responsible under the Agreement with respect to the terminated Product(s) and [***] Product(s), and any milestones achieved and royalty payments pursuant to **Section 3.1** with respect to the terminated Product(s), as of the Termination Date within sixty (60) days following receipt from Momenta of a detailed invoice therefore;

(x) Momenta shall reimburse CSL for [***] and [***] with the [***] of the [***]; and

(xi) If this Agreement is terminated in its entirety only:

(1) Momenta shall have the right, at its sole cost and expense, to prosecute, maintain and enforce any Joint Patent Rights covered by the license in **Section 11.7(a)(iv)** ;

(2) CSL shall use Commercially Reasonable Efforts to promptly transfer to Momenta or its designee (A) copies of all data, reports, records and materials in CSL's possession or control which relate to any Momenta Intellectual Property comprised in the [***] Products; (B) all records and materials in CSL's possession or control containing Confidential Information of Momenta which relates to Momenta Intellectual Property comprised in the [***] Products; and (C) [***] and [***] to [***] reasonable costs and expenses [***] or [***] which relate to Momenta Intellectual Property comprised in the [***]; and

(3) Momenta shall use Commercially Reasonable Efforts to promptly transfer to CSL or its designee (A) copies of all data, reports, records and materials in Momenta's possession or control which relate to any CSL Intellectual Property comprised in the [***] Products; (B) all records and materials in Momenta's possession or control containing Confidential Information of CSL which relates to CSL Intellectual Property comprised in the [***] Products; and (C) [***] and [***] to [***] and [***] or [***] which relate to CSL Intellectual Property comprised in the [***].

(b) **Termination Where CSL Has the Right to Continue and Retain Rights to the Product(s).** Without limiting any other legal or equitable remedies that either Party may have, if this Agreement or a Product under the Agreement is terminated:

- by CSL under [***],
- by CSL [***] under [***],
- by CSL [***] or [***] under [***]; or
- by CSL [***] under [***],

the following provisions will take effect as of the effective date of the Termination Date with respect to the Product(s) for which the Agreement has terminated:

(i) Momenta will, as soon as practicable, transfer to CSL or its designee: (A) copies of all data, reports, records and [***] in [***] relating to the Development, Manufacture or Commercialization of the terminated Product(s), including all [***] and [***] relating to the terminated Product(s), [***] (B) all inventory of terminated Product(s) [***] or [***]; and (C) all records and materials [***] or [***] Confidential Information of CSL relating solely to the terminated Product(s);

(ii) If, at the time of termination, Momenta is performing Manufacturing activities for the terminated Product(s), Momenta shall upon [***] and [***] to [***] to [***] and [***] associated therewith, [***] to effect a transfer of such activities to CSL or a Third Party nominated by CSL. If CSL so requests, Momenta will assign to CSL any agreements with Third Parties reasonably necessary for and primarily relating to the Development, Manufacture or Commercialization of the terminated Product(s) to which Momenta is a party to the extent permitted by the terms of such agreements; provided , however , that Momenta shall not be [***] to [***] to [***] or [***];

(iii) If Momenta is Co-Funding one or more Products, Momenta shall submit payment to CSL for any amounts paid by CSL related to Program Expenses incurred through the Termination Date for which Momenta is responsible for under the Agreement with respect to the terminated Product(s), within [***] receipt from CSL of a detailed invoice therefore;

(iv) the licenses granted to Momenta in **Article 2** (other than the license granted under **Section 2.3** with respect to Joint Intellectual Property) will terminate with respect to the terminated Product(s) (or entirely if the whole Agreement is terminated);

(v) CSL shall, with respect to the terminated Products, continue to exercise the licenses and rights granted to CSL under **Article 2,** subject to the revised royalty rates set forth below, replacing the royalty rates set out in **Section 3.1(e)(i)** , and with the same reporting obligations and other obligations related to the payment of such royalties as would have applied under this Agreement. No other royalties or milestones will be payable with respect to the terminated Product(s). CSL shall have the right to terminate such licenses at any time. The revised royalty rates are as follows:

(1) If the Agreement is terminated prior to the [***] a [***] Trial for a terminated Product(s), CSL shall pay to Momenta a royalty of [***] of Net Sales of such Product(s) during the Royalty Period;

(2) If the Agreement is terminated after [***] a [***] and [***] the [***] a [***], CSL shall pay to Momenta a royalty of [***] of Net Sales of such Product during the Royalty Period; and.

(3) If the Agreement is terminated on or after the [***] terminated Product, CSL shall pay to Momenta a royalty of [***] of Net Sales of such Product during the Royalty Period;

(vi) until the expiry of CSL's obligation to pay royalties under **Section 11.7(b)(v)** , CSL shall provide Momenta with quarterly reports of Net Sales in relation to the terminated Product(s) in a level of detail equivalent to Net Sales Statements; and.

(vii) if this Agreement is terminated in its entirety only:

(1) CSL shall have the right, at its sole cost and expense, to prosecute, maintain and enforce any Joint Patent Rights; and.

(2) Momenta shall use Commercially Reasonable Efforts to promptly transfer to CSL or its designee (A) copies of all data, reports, records and materials in Momenta's possession or control which relate to the [***] Products; (B) all records and materials in Momenta's possession or control containing Confidential Information which relates to the [***] Products; and (C) [***] and [***] to [***] to [***] and [***] of [***] associated therewith, [***] or [***] which relate to [***].

(c) **Termination Prior to the** [***] **the** [***] **.** Without limiting any other legal or equitable remedies that either Party may have, if this Agreement is terminated:

- by CSL [***] its [***] under [***] (Prior to [***]), or
- by Momenta under [***] terminates prior to [***] of [***]),

the following provisions will take effect as of the Termination Date with respect to the Agreement:

(i) the consequences set out in **Section 11.7(a)** shall apply, provided that the license specified in **Section 11.7(a)(iv)** shall not be granted by CSL to Momenta;

(ii) Each Party shall grant to the other Party and its Affiliates a [***] to [***] in which it or its Affiliates has an ownership interest at the termination date [***] the [***] the [***] to [***];

(iii) despite anything to the contrary in **Section 11.7(a),** the provisions of this Agreement relating to the [***] of [***] to [***];

(iv) subject to the licenses granted to the other Party under this Agreement and any other terms of this Agreement that survive termination, each Party has a right to exploit its interest in the Joint Intellectual Property without the consent of and without accounting to the other Party; and

(v) no further royalties or milestones will be payable by either Party except for the royalty payable under **Section 11.7(a)(v)** .

(d) **[***] Products** . [***] Products are not subject to separate termination on a [***] Product by [***] Product basis under this Agreement. Subject to the provisions of any licenses granted or surviving on termination, on termination of the Agreement in its entirety, each Party will be free to exploit any Intellectual Property owned by it comprised in the [***] Products.

11.8 **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.

11.9 **Survival of Liability** . Expiration or termination of this Agreement for any reason shall not release either Party from any liability that, at the time of such expiration or termination, has already accrued or that is attributable to a period prior to such expiration or termination, nor preclude either Party from pursuing any right or remedy it may have hereunder or at law or in equity with respect to any breach of this Agreement.

11.10 **Survival** . Termination or expiration of this Agreement for any reason will be without prejudice to any rights that have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement or prevent a Party from exercising any rights that are expressly indicated to survive such termination or expiration. Upon termination or expiration of this Agreement as provided for in this **Article 11** , the following Articles and Sections of this Agreement shall survive:

(a) **Article 1** (Definitions);

(b) **Article 2 (Licenses),** but solely with respect to the subject matter of the following provisions, and solely to the extent required to give effect to and subject to the provisions of:

(i) **Section 11.7(b)(v)** (CSL's right to continue to exercise the licenses and rights granted to CSL under **Article 2** on termination by CSL where CSL has right to continue);

(ii) **Section 11.7(a)(iv)** (licenses to CSL survive solely to the extent necessary to enable CSL to perform its obligations under Section **11.7** with respect to the terminated Products on termination by Momenta where Momenta has right to return of the Product(s));

(iii) **Section 2.1(c)** (providing for exercise of rights by Affiliates);

(iv) **Section 2.3** (Joint Intellectual Property);

(v) **Section 2.7** (Retained Rights);

(vi) **Section 2.9** (No Additional Licenses);

(vii) **Section 2.10(a)** (Bankruptcy); and

(viii) The limited license granted by CSL to Momenta with respect to New Intellectual Property, as provided in the final sentence of Section **2.2;**

(c) **Section 3.5** (Currency);

(d) **Section 4.5** (Overdue Payments);

(e) **Article 3** (Financial Terms) (with respect to earned payments and royalties as of the effective date of termination and the reporting of Net Sales and payments thereof under royalties payable post-termination under **Section 11.7**);

(f) **Section 4.3** (Cost Share and Profit Share for Co-Funding of Products and [***] Products) (solely with respect to unreported, unreconciled and Program Expenses, Profits and Losses as of the effective date of termination to facilitate the final payment and Reimbursement to a Party related thereto);

(g) **Section 4.6** (Taxes) **;**

(h) **Section 4.7** (Audits; Records and Inspections);

(i) **Section 7.1** (Ownership of Intellectual Property);

(j) **Section 7.4** (Enforcement and Defense of Enforcement Intellectual Property) (but solely where, pursuant to Section 11.7(b)(v), CSL has the right to continue to exercise the licenses and rights granted to CSL under Article 2 on termination by CSL where CSL has right to continue);

(k) **Section 7.3(a)** (Trademarks and Domain Names) (ownership of provision) **;**

(l) **Article 8** (Confidential Information) other than **Section 8.2** (Public Disclosure) **;**

(m) **Article 9** (Indemnification and Limitation of Liability) other than **Section 9.4(Insurance);**

(n) **Article 11** (Term and Termination); and

(o) **Article 13 (Miscellaneous)** other than **Sections 13.3(b)** (Change of Control) **; Section 13.8** (Quality Agreement) **; Section 13.11** (Dispute Resolution); **Section 13.12** (HSR Act) **;** and **Section 13.13** (Anti-Corruption Audits and Inspections) **.**

For the avoidance of doubt, if CSL has obtained, under **Section 3.1(e)(vi)** , upon the expiration of the Royalty Period with respect to any Product in any particular country in the Territory, a fully paid-up, perpetual, irrevocable, exclusive license in such country to the Momenta Intellectual Property to research, Develop, make, use, import, sell, have made, have sold and otherwise Commercialize such Product, such license shall not be affected by the subsequent termination or expiration of this Agreement.

ARTICLE 12.
REPRESENTATIONS, WARRANTIES AND COVENANTS

12.1 **Momenta** . Momenta represents and warrants that, as of the Execution Date: (a) it has the full right, power and authority to enter into this Agreement and to grant the rights and licenses granted by it hereunder; (b) to the knowledge of Momenta, there are no existing or threatened actions, suits or claims pending with respect to the subject matter hereof or the right of Momenta to enter into and perform its obligations under this Agreement; (c) it has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; (d) this Agreement has been duly executed and delivered on behalf of it, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof; and (e) the execution and delivery of this Agreement and the performance of its obligations hereunder do not conflict with or violate any requirement of Applicable Law or regulations and do not conflict with, or constitute a default under, any contractual obligation of Momenta.

12.2 **CSL** . CSL represents and warrants that as of the Execution Date: (a) it has the full right, power and authority to enter into this Agreement and to grant the rights and licenses granted by it hereunder; (b) to the knowledge of CSL, there are no existing or threatened actions, suits or claims pending with respect to the subject

matter hereof or the right of CSL to enter into and perform its obligations under this Agreement; (c) it has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; (d) this Agreement has been duly executed and delivered on behalf of it, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof; and (e) the execution and delivery of this Agreement and the performance of its obligations hereunder do not conflict with or violate any requirement of Applicable Law or regulations and do not conflict with, or constitute a default under, any contractual obligation of CSL.

12.3 **Additional Representations and Warranties by Momenta.** In addition to the representations and warranties given by Momenta elsewhere in this **Article 12** , Momenta hereby also represents, warrants, and covenants to CSL that, to the best of its actual knowledge at the Execution Date, and other than those matters which have been disclosed, in writing, by Momenta to CSL prior to the signing of this Agreement:

(a) it has not previously assigned or transferred its right, title and interest in any item of Momenta Patent Rights listed in **Schedule 1.93** ;

(b) it has the right to grant the license and rights herein to CSL and it has not granted any license, right or interest in, to or under the Momenta Patent Rights listed in **Schedule 1.93** or any Momenta Know-How that is [***] and [***] the [***] the [***] under this Agreement to any Third Party;

(c) the Development, use, sale and importation of Products [***] or [***] and does not [***] of [***] or [***] a [***];

(d) there are no claims, judgments or settlements against or owed by Momenta and there are no pending or threatened claims or litigation; in each case relating to the Momenta Patents or Momenta Know-How;

(e) [***] the [***] and [***] the [***] or [***] as of, the Execution Date have been and are being conducted in accordance with Applicable Laws;

(f) [***] the [***] and, are [***] or [***], in whole or in part;

(g) it has and will have the full right, power and authority to grant all of the right, title and interest in the licenses granted or to be granted to CSL under this Agreement; with the acknowledgement that non-exclusive license that held by Momenta can only be granted exclusively as to CSL and are not exclusive as to Third Parties;

(h) **Schedule 1.93** contains a complete and correct list of all Momenta Patents related to [***] existing as of the Execution Date, including any exclusive license rights, and the Momenta Patent Rights listed in **Schedule 1.93** are existing and, with respect to any patents listed in **Schedule 1.93** Momenta (i) is not aware of any claim made against it asserting the invalidity, misuse, unregisterability, unenforceability or non-infringement of any of such Momenta Patent Rights and (ii) is not aware of any claim made against it challenging Momenta' Control of such Momenta Patent Rights or making any adverse claim of ownership or the rights of Momenta to such Momenta Patent Rights;

(i) are not aware of any Third Party that is infringing any of the Momenta Patents;

(j) other than as set out in **Schedule 1.93** there are no exclusive license rights held by Momenta with respect to the composition, method of making, or method of use of the [***] Product;

(k) the Momenta Patent Rights listed in **Schedule 1.93** and any Momenta Know-how that is material to and would interfere with the exercise of the licenses granted under this Agreement existing as of the Execution Date are not subject to any funding agreement with any government or government agency which is inconsistent with the rights granted to CSL under this Agreement;

(l) with regard to any invention claimed in the Momenta Patent Rights which was conceived, reduced to practice, developed, made or created by Momenta's employees, Momenta has:

(i) [***] or [***] on [***] on [***] to [***] to [***] the [***] or [***] of [***]

(ii) [***] and [***] to [***] to [***] or [***] or [***] the [***] and [***] or [***] the [***] or [***] the [***] or [***] or [***] of [***].

12.4 **No Debarment** . Each Party represents and warrants to the other Party that such Party, and such Party's employees, officers, independent contractors, consultants, or agents who will render services relating to the Products and the [***] Products: (a) have not been debarred and are not subject to debarment or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. § 335a (or its equivalent under Applicable Law); and (b) have never been under indictment for a crime for which a person or entity could be debarred under said § 335a (or its equivalent under Applicable Law). If during the Term, a Party has reason to believe that it or any of its employees, officers, independent contractors, consultants, or agents rendering services relating to the Products and the [***] Products: (x) is or will be debarred or convicted of a crime under 21 U.S.C. § 335a (or its equivalent under Applicable Law); or (y) is or will be under indictment under said § 335a (or its equivalent under Applicable Law), then such Party shall immediately so notify the other Party in writing.

12.5 **Compliance with Applicable Law** . Each Party shall carry out all work assigned to such Party in the applicable Product Work Plan(s) and its other obligations under this Agreement in material compliance with all Applicable Law, including: (a) the Food, Drug, and Cosmetic Act and any applicable implementing regulations, and relevant non-U.S. equivalents thereof; (b) GMPs; (c) GCPs, (d) all other applicable FDA guidelines and relevant guidelines of applicable regulatory authorities; (e) all other Applicable Laws and regulations, including all applicable federal, national, multinational, state, provincial and local environmental, health and safety laws and regulations in effect at the time and place of Manufacture of a Product or a Research Product; (f) all applicable export and import control laws and regulations; and (g) all applicable anti-bribery and anti-corruption laws and regulations.

12.6 **Commercialization of Products** . Each Party agrees, on behalf of itself and its Affiliates and Sublicensees, not to materially and artificially discount the price of a Product solely to generate sales of other products commercialized by such Party (either its own products or those of its Affiliates or Sublicensees).

12.7 **Anti-Corruption Laws** . Each Party represents, warrants and covenants that it will comply with the U.S. Customs & Trade Partnership Against Terrorism and with the laws and regulations relating to anti-corruption and anti-bribery including the U.S. Foreign Corrupt Practices Act (collectively, the " **Anti-Corruption Laws** "). Each Party further represents and warrants that no one acting on its behalf will give, offer, agree or promise to give, or authorize the giving directly or indirectly, of any money or other thing of value to anyone as an inducement or reward for favorable action or forbearance from action or the exercise of influence (a) to any governmental official or employee (including employees of government-owned and government-controlled corporations or agencies), (b) to any political party, official of a political party, or candidate, (c) to an intermediary for payment to any of the foregoing, or (d) to any other person or entity in a corrupt or improper effort to obtain or retain business or any commercial advantage, such as receiving a permit or license.

(a) Each Party understands that the other Party may immediately suspend payment, in its sole discretion and without notice, if the actions or inactions of such Party become subject to an investigation of potential violations of the Anti-Corruption Laws. Moreover, each Party understands that if it fails to comply with the provisions of the Anti-Corruption Laws, the other Party may terminate this Agreement, and any payments due thereunder, pursuant to **Section 11.5** .

(b) Each Party warrants that all persons acting on its behalf will comply with all Anti-Corruption Laws in connection with all work performed hereunder prevailing in the country(ies) in which each Party has its principal places of business or performs such work.

12.8 **Disclaimer** . EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF TECHNOLOGY OR PATENT CLAIMS, WHETHER ISSUED OR PENDING.

ARTICLE 13.
MISCELLANEOUS

13.1 **Governing Law** . This Agreement shall be governed by, interpreted and construed in accordance with the substantive laws of the State of New York in the United States, without regard to conflicts of law principles.

13.2 **Amendment; Waiver** . This Agreement may only be amended or waived in a document that expressly states the Article or Section that is being modified or waived and that is signed by the Parties. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance.

13.3 **Assignments; Change in Control** .

(a) **Assignment.** Neither this Agreement nor any right or obligation hereunder may be assigned or delegated, in whole or part, by either Party without the prior written consent of the other or pursuant to subcontracting or sublicensing arrangements expressly contemplated herein; provided , however , that either Party may, without the written consent of the other, assign this Agreement and its rights and delegate its obligations hereunder in connection with the transfer or sale of all or substantially all of its business or in the event of its merger, consolidation, change in control or similar transaction. Notwithstanding the foregoing, either Party may, without the written consent of the other, assign this Agreement and its rights and delegate its obligations hereunder to an Affiliate; provided that neither Party may, [***] the [***] the [***] or [***] of [***] to [***] Any permitted assignee shall assume all obligations of its assignor under this Agreement; provided that such assignor shall remain primarily liable for the performance hereunder of such assignee. Any purported assignment in violation of this **Section 13.3** shall be null and void. Notwithstanding anything to the contrary set forth herein, if a Party (the " **Assigning Party** ") assigns or transfers this Agreement to a Third Party (any such Third Party, a " **Transferee** "), whether by merger, assignment, transfer of assets, or operation of law, then the [***] that were [***] or [***] by such [***] to or [***] such assignment or [***] (other than [***] by such [***] in the course of [***] the [***] under this Agreement to the extent such [***] would [***] been so [***] had it been [***] or [***] to [***] by [***]) shall not be deemed to [***], [***] or other [***] or [***] by such [***], and shall also not be [***] or otherwise [***] in any manner, including without limitation, by being [***] to any [***] of or [***] this [***]. Furthermore, such [***] (and [***] of such [***]: (a) [***] immediately prior to such merger, acquisition, assignment or transfer; or (b) [***] or [***] such merger, acquisition, assignment or transfer, in each case which are not [***] by (as defined under the [***] definition in [***]) the [***]) shall be excluded from the [***] for purposes of determining [***] that are [***] to this [***].

(b) **Change of Control** .

(i) **Momenta Change of Control** . Notwithstanding anything to the contrary in **Section 13.3(a)** , in the event that Momenta is subject to a Change of Control (whether or not this Agreement is assigned in connection with such Change of Control), Momenta shall, within [***] after the date that such Change of Control closes (the " **Momenta COC Closing Date** "), provide CSL with notice of such Change of Control (" **Momenta COC Notice** "). In the event of a Change of Control of Momenta, then:

(1) Upon CSL's written election after receipt of such Momenta COC Notice (which election shall be made by providing notice thereof (" **CSL COC Election Notice** ") no later than [***] after receipt of the Momenta COC Notice), and effective as of the Momenta COC Closing Date (or the Effective Date, if later) solely if CSL provides such CSL COC Election Notice:

(A) CSL shall retain all licenses granted under this Agreement and shall retain the exclusive right to Develop, Manufacture and Commercialize the Products in the Territory;

(B) If Momenta is Co-Funding prior to the Change of Control, Momenta will retain its Opt-Out Options under this Agreement. If Momenta has not exercised a Co-Funding Option, Momenta shall forfeit its Co-Funding Option if it has not expired;

(C) Momenta shall promptly transfer to CSL or its designee all Development, Manufacturing, and Commercialization Activities under any Product Work Plan. Momenta shall also transfer its control of any Enforcement and Defense of Intellectual Property activities under **Section 7.4** pertaining to CSL Intellectual Property and Joint Intellectual Property for the Products in the Territory and CSL shall assume control thereof and the provisions of **Subsections 11.7(b)(i)** to **11.7(b)(iv)** (inclusive) shall apply;

(D) CSL shall not be obligated to submit any further updates to the Product Work Plan or the Commercialization Plan to Momenta;

(E) Except as provided in (F) below, Momenta shall [***] or [***] the [***] and the [***] and [***];

(F) CSL shall have no further reporting or record-keeping obligations hereunder with respect to the Development, Manufacture or Commercialization of, and regulatory activities for, the Products other than: (x) its financial reporting and record-keeping obligations, and audit rights, to the extent necessary to verify the accuracy of the calculation of royalties, milestones or other amounts paid or payable to Momenta and to provide to Momenta, if Momenta is Co-Funding any Product, the information to be provided in the Reimbursement and Co-Funding Report provided for in **Section 4.3(c),** based on the then-effective terms of the Agreement, as applicable; and (y) provision of updates regarding anticipated timelines for Regulatory Approvals and Launches of the Products and budgets associated with such timelines;

(G) CSL shall have the right to terminate any Co-Promotion Agreements and Momenta's Co-Promotion Options in the U.S. by providing written notice of such termination to Momenta within [***] after sending the CSL COC Election Notice;

(H) Unless CSL specifies otherwise in its Momenta COC Notice, if there is an existing Research Plan at time of Change of Control, the Research Plan shall terminate; and

(I) All licenses of Intellectual Property granted by CSL to Momenta under this Agreement shall terminate. Except as otherwise expressly provided in this **Section 13.3(b)(i)** , each Party shall continue to have the same rights and obligations to receive royalties and milestone payments and, if applicable, to share or require the sharing of Program Expenses, Profits and Losses, and, in the case of Momenta, to exercise its Opt-Out Option, in each case as applicable under the terms of the Agreement in effect immediately prior to the Change of Control.

(ii) **CSL Change of Control** . Notwithstanding anything to the contrary in **Section 13.3(a)** , in the event that CSL is subject to a Change of Control (whether or not this Agreement is assigned in connection with such Change of Control), CSL shall, within [***] after the date that such Change of Control closes (the " **CSL COC Closing Date** "), provide Momenta with notice of such Change of Control (" **CSL COC Notice** "). In the event of a Change of Control of CSL, then:

(1) Upon Momenta's written election after receipt of such CSL COC Notice (which election shall be made by providing notice thereof (" **Momenta COC Election Notice** ") no later than [***] after receipt of the CSL COC Notice), and effective as of the CSL COC Closing Date (or the Effective Date, if later) solely if Momenta provides such Momenta COC Election Notice, Momenta shall have:

(A) the right to terminate any Co-Promotion agreement and/or the Research Plan;

(B) The right to opt out of Co-Funding any Product on a Product by Product basis or with regard to all Products by giving an Opt-Out Notice under **Section 4.2(b)** ; and **Section 4.2(b)** shall be deemed to be amended to allow for an opt-out of Co-Funding on Product-by-Product basis; and

(C) Each Development Plan then in effect shall be subject to review and approval by the JSC in accordance with **Section 5.2** in the same manner as provided for an initial Development Plan for each Product.

(2) Except as otherwise expressly provided in this Section 13.3(b)(ii), each Party shall continue to have the same rights and obligations under the **Agreement** , including without limitation, the right to receive royalties and milestone payments and, if applicable, to share or require the sharing of Program Expenses, Profits and Losses, and, in the case of Momenta, to exercise its Opt-Out Option, in each case as applicable under the terms of the Agreement in effect immediately prior to the Change of Control.

13.4 **Independent Contractors** . The relationship of the Parties hereto is that of independent contractors. The Parties hereto are not deemed to be agents, partners or joint ventures of the others for any purpose as a result of this Agreement or the transactions contemplated thereby.

13.5 **Notices** . Any notice required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and (a) sent by certified or registered mail, return receipt requested, postage prepaid, (b) sent by an internationally recognized overnight courier service, (c) sent by hand delivery, to the representative for such Party at the address set forth below for such Party, or (d) sent by electronic mail to the representative for such party at the electronic mail address set forth below for such Party. If a Party changes its representative or address, written notice shall be given promptly to the other Party of the new representative or address. Notice shall be deemed given on the third (3rd) Business Day after being sent in the case of delivery by mail, on the first (1st) Business Day after being sent in the case of delivery by overnight courier, on the date of delivery in the case of delivery by hand, and upon receipt by the Party giving notice of an electronic mail message from the Party to which notice is being given acknowledging acceptance in the case of electronic mail. The addresses of the Parties and representatives are as follows:

If to Momenta:
Momenta Pharmaceuticals, Inc.
675 West Kendall Street
Cambridge, MA 02142
USA
Attn: President and CEO
Facsimile: [***]

With a copy to:
Momenta Pharmaceuticals, Inc.
675 West Kendall Street
Cambridge, MA 02142
USA
Attn: General Counsel
Email: [***]

If to CSL:
CSL Behring Recombinant Facility AG
Wankdorfstrasse 10
3000 Bern 22
Switzerland
Attention: Senior Director, Legal Affairs
Facsimile: [***]

With a copy to:
CSL Limited
45 Poplar Road
Parkville Vic 3052
Australia
Attention: Company Secretary
Email: [***]

13.6 **Force Majeure** . Neither Party shall be held liable or responsible to the other nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement (excluding payment obligations) to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of such Party including but not limited to fires, earthquakes, floods, embargoes, wars, acts of war (whether war is declared or not), terrorist acts, insurrections, riots, civil commotion, and other similar causes. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline

or time for performance specified in a Product Work Plan that falls due during or subsequent to the occurrence of any of the disabilities referred to herein shall be automatically extended for a period of time equal to the period of such disability. Each Party shall immediately notify the other if, by reason of any of the disabilities referred to herein, it cannot meet any deadline or time for performance specified in any Exhibit to this Agreement. The Parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from this force majeure. If a condition constituting force majeure, as defined herein, exists for more than one-hundred eighty (180) consecutive days (a) with respect to a Product or a [***] Product, then either Party may terminate the Agreement solely with respect to such Product or [***] Product, or (b) that affects all Products and [***] Products, either Party may terminate this entire Agreement. The consequences of such termination are set forth in **Section 11.7** .

13.7 **Complete Agreement** . This Agreement constitutes the entire agreement, both written and oral, between the Parties with respect to the subject matter hereof, and all prior agreements respecting the subject matter hereof, whether written or oral, expressed or implied, shall be of no force or effect, including the Prior Confidentiality Agreement and the Prior Material Transfer Agreement (subject to **Section 8.5**).

13.8 **Quality Agreement** . The Parties shall enter into a quality agreement relating to any GMP Product to be manufactured under a Product Work Plan by or for Momenta on behalf of CSL prior to initiating any GMP activities under the Product Work Plan.

13.9 **Severability** . If any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Agreement shall remain in full force and effect without such provision. In such event, the Parties shall in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the Parties in entering this Agreement.

13.10 **Counterparts** . This Agreement may be executed in counterparts, each of which shall be deemed to be an original and both together shall be deemed to be one and the same agreement. Counterparts may be signed and delivered by facsimile, or electronically in PDF format, each of which will be binding when sent.

13.11 **Dispute Resolution** . The Parties recognize that bona fide disputes may arise that relate to the Parties' rights and obligations under this Agreement. Where this Agreement does not specifically provide for a mechanism to resolve such Disputed Matter, the Parties shall follow the procedure set out in this section:

(a) **Executive Resolution** . In attempting to resolve any Disputed Matters, the Disputed Matter shall first be elevated through each Party's respective executive management representatives having responsibility for the function or Activity in respect of which such dispute occurs.

(b) **Mediation** . If executive management representatives are unable to resolve a Disputed Matter within [***] after such matter is referred to such executive management representatives, and final decision-making in respect of such Disputed Matter is not otherwise conferred upon CSL by the terms of this Agreement, the Parties shall, for Disputed Matters other than those arising under **Section 3.1(g),** then submit the matter for non-binding mediation under the [***]. The Parties will select a mediator on an expedited basis and seek to mediate the matter with in [***] of referral to mediation.

(c) **Arbitration except in respect of matters arising under Sections [***] and [***]** . Subject to **Sections [***]** and **[***]** , where a Disputed Matter remains unresolved [***] after referral to executive management representatives pursuant to **Section 13.11(a)** and final decision-making in respect of such Disputed Matter is not otherwise conferred upon CSL by the terms of this Agreement, and, following such failure of executive management resolution, mediation pursuant to **Section 13.11(b)** (as applicable) has been unsuccessful, a Party seeking further resolution of the Disputed Matter shall submit the Disputed Matter to resolution by final and binding arbitration in accordance with [***] in effect on the date of this Agreement and applying the substantive law specified in **Section 13.1** . For the purposes of this **Section 13.11** , these rules and supplementary procedures shall be called the " **Rules** ". Whenever a Party decides to institute arbitration proceedings, it shall give written notice to that effect to the other Party, and the place of arbitration will be in [***]. The arbitration will be conducted by a panel of three (3) arbitrators, who will be appointed as follows: the Parties shall attempt to jointly select such arbitrators. If the Parties cannot agree on the three arbitrators, then the arbitrators will be appointed by [***] in accordance with the Rules. Each arbitrator must have business or legal experience in the biologic pharmaceutical industry and any additional experience set forth in **Section 6.8(c)** , if such Disputed Matter arises under such section. Decisions of the arbitrators that conform to the terms of this **Section 13.11(c)** shall be final and binding on the Parties, and judgment on the award so rendered may be entered in any court of competent jurisdiction.

(d) **Arbitration in relation to matters arising under Sections [***] and [***]** . As explicitly provided for in **Sections [***] and [***]** , if executive management resolution and then mediation do not resolve the relevant Disputed Matter, the Parties shall then submit the relevant Disputed Matter for arbitration pursuant to the [***], using a single arbitrator who will be agreed by the Parties or, should the Parties fail to reach agreement within [***], will be selected in accordance with the [***]. Unless otherwise agreed to by the Parties, the arbitrator shall not be the same as the mediator, and must have business or legal experience in the biologic pharmaceutical industry. The arbitrator shall have sole responsibility of resolving such Disputed Matter from a case and proposal submitted by each Party under this **Section 13.11(d)** , and no other Disputed Matters, claims or counterclaims will be permitted by the Parties in such arbitration. Within [***] after selection of the arbitrator, each Party shall submit to the arbitrator, and exchange with the other Party in accordance with a procedure to be established by the arbitrator, its case and proposal for resolving such Disputed Matter. Within [***] after receiving each Party's case and proposal, the arbitrator shall select, in its entirety and without modification, solely one (1) of the two (2) proposals submitted by the Parties. Decisions of the arbitrator that conform to the terms of this **Section 13.11(d)** shall be final and binding on the Parties for the purpose of [***] of the relevant Product; provided that it shall not affect CSL's right under this Agreement, exercisable at any time, [***] to [***] with [***] and [***] of such [***].

(e) The Parties shall each bear or pay [***] of the administrative costs and fees of any arbitration under **Section 13.11(c)** and/or **13.11(d)** and the arbitrators' award will so provide. Each Party shall also bear or pay its own attorneys' fees, expert or witness fees, and any other fees and costs, and no such fees or costs will be shifted to the other Party. Except as may be required by Applicable Law, no Party (or its representative, witnesses or arbitrators) may disclose the existence, content or result of any arbitration under this Agreement without the prior written consent of both Parties, except that no such consent shall be required to enter and enforce the judgment in court.

(f) **Non-arbitrated Disputes** . Notwithstanding anything in this Agreement to the contrary, as between the Parties, any and all issues regarding: (i) the infringement, validity and enforceability of any patent in a country, (ii) the termination of this Agreement (other than termination for failure to use Commercially Reasonable Efforts), (iii) any Disputed Matter that occurs after the termination of the Agreement and (iv) any decision of CSL under **Section 5.14** not to continue with Development and/or Commercialization of the First Product (collectively " **Non-Arbitrated Matters** ") shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction. To the extent that such Non-Arbitrated Matters are litigated in a court in the United States, the parties agree to file any such dispute in the United States District Court for the [***], with each party waiving its right to object due to lack of personal jurisdiction, improper or inconvenient venue, or other reasons. Subject to the provisions of **Section 11.4** (Termination for Patent Challenge), the parties reserve the right to challenge the validity of patents in the Patent Trial and Appeal Board of the U.S. Patent Office. If such Non-Arbitrated Matters involve other related Disputed Matters, the Parties agree that all such matters shall be litigated together in court and without arbitration.

(g) **Equitable Relief** . Notwithstanding anything in this Agreement to the contrary, nothing in this Agreement shall prevent either Party from seeking equitable relief from any court of competent jurisdiction to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrators on the ultimate merits of any Disputed Matter. Any such request shall not be deemed incompatible with the agreement to arbitrate or a waiver of the right to arbitrate.

13.12 **HSR Act** . The Parties shall use Commercially Reasonable Efforts to promptly obtain any clearance required under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (15 U.S.C. § 18a) (the " **HSR Act** ") for the consummation of this Agreement and the transactions contemplated hereby. Each Party shall furnish to the other Party reasonably necessary information and reasonable assistance as the other Party may request in connection with its compliance with the HSR Act, and any inquiries or requests for additional information in connection therewith. Each Party shall pay all of its costs and expenses related to any filing by such Party pursuant to the HSR Act, save that the parties shall each pay one half of the filing fee for such filing. The Parties shall request early termination of the waiting period for clearance under the HSR Act. Each Party shall provide the other Party with notice of achievement of the HSR clearance on the HSR Clearance Date or promptly thereafter as practical. Other than the provisions of **Article 12** and this **Section 13.12** , the rights and obligations of the Parties under this Agreement shall not become effective until the HSR Clearance Date, at which time they shall be immediately effective. If the HSR Clearance Date has not been granted within one hundred twenty (120) days after the Execution Date, either Party may terminate this Agreement by written notice to the other Party. Except for **Article 8** , none of the provisions of this Agreement (for clarity, including **Section 11.7** and **Section 11.9**), shall remain in effect after such termination.

13.13 **Anti-Corruption Audits and Inspection** . Upon sixty (60) days' prior written notice from a Party, the other Party shall permit, and shall ensure that its Affiliates and Sublicensees shall permit representatives and/or agents of the requesting Party, at the requesting Party's expense, to have access to such Party's (or their Affiliates' or Sublicensees') records, as may be reasonably necessary to verify the non-requesting Party's compliance with **Section 12.7** ; provided that a Party may not request to conduct such an audit of the other Party more than once per calendar year.

13.14 **Captions; Certain Conventions; Construction** . All captions herein are for convenience only and shall not be interpreted as having any substantive meaning. The Exhibits to this Agreement are incorporated herein by reference and shall be deemed a part of this Agreement. Unless otherwise expressly provided herein or the context of this Agreement otherwise requires: (a) words of any gender include each other gender; (b) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (c) words using the singular shall include the plural, and vice versa; (d) the words "include," "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation", "inter alia" or words of similar import; and (e) references to "Article," "Section," "subsection", "clause", or other subdivision, or Exhibit, without reference to a document are to the specified provision or Exhibit of this Agreement. If the terms of this Agreement conflict with the terms of any Exhibit, the terms of this Agreement shall prevail. References to either Party include the successors and permitted assigns of that Party. The Preamble, Recitals and Exhibits are incorporated by reference into this Agreement. The Parties have each consulted counsel of their choice regarding this Agreement, and, accordingly, no provisions of this Agreement will be construed against either Party on the basis that the Party drafted this Agreement or any provision thereof. The official text of this Agreement and any Exhibit, any notice given or accounts or statements required by this Agreement, and any dispute proceeding related to or arising hereunder, will be in English. If any dispute concerning the construction or meaning of this Agreement arises, then reference will be made only to this Agreement as written in English and not to any translation into any other language.

[*Signature Page Follows*]

[*Signature Page to License and Option Agreement*]

IN WITNESS WHEREOF, the Parties hereto have set their hand as of the Execution Date.

MOMENTA PHARMACEUTICALS, INC.

By: /s/ Craig A. Wheeler
Name: Craig A. Wheeler
Title: President and Chief Executive Officer

CSL BEHRING RECOMBINANT FACILITY AG by its duly authorized attorney

By: /s/ David Lamont
Name: David Lamont
Title: Chief Financial Officer

SCHEDULE 1.33

CALCULATION OF LABOR COSTS, EXPENSE ALLOCATION AND RELATED MATTERS

[***]

Confidential Portions of this Exhibit marked as [***] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

SCHEDULE 1.93

MOMENTA PATENT RIGHTS

[***]

Confidential Portions of this Exhibit marked as [***] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

SCHEDULE 1.135

TECHNOLOGY TRANSFER PLAN – OUTLINE OF CMC ASPECTS

[***]

Confidential Portions of this Exhibit marked as [***] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

SCHEDULE 5.2(b)

OUTLINE OF INITIAL DEVELOPMENT PLAN FOR FIRST PRODUCT

[***]

Confidential Portions of this Exhibit marked as [***] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

EXHIBIT 8.2

INITIAL PRESS RELEASE

MOMENTA PHARMACEUTICALS, INC . 675 WEST KENDALL STREET T: 617.491.9700
WWW.MOMENTAPHARMA.COM CAMBRIDGE, MA 02142 F: 617.621.0430

Momenta and CSL Announce Collaboration and License Agreement to Develop Fc Multimer Programs, Including M230, a Selective Immunomodulator of Fc Receptors

--Momenta to receive $50 million upfront license fee and up to $550 million in potential milestone payments from CSL--

--Momenta to host a conference call for its investors today at 4:30 PM ET--

CAMBRIDGE, MA — January 5, 2017 —Momenta Pharmaceuticals, Inc. (Nasdaq: MNTA) and CSL Limited (ASX:CSL; USOTC:CSLLY) today announced that they have entered into an exclusive research collaboration and worldwide license agreement to develop and commercialize Fc multimer proteins, including Momenta's M230, a selective immunomodulator of Fc receptors, which is expected to enter the clinic in 2017. Momenta will receive a $50 million upfront license fee from CSL and is eligible to receive future milestone and royalty payments for M230. In addition to advancing M230, CSL and Momenta intend to enter into a research collaboration to develop additional Fc multimer proteins that may originate from Momenta's or CSL's research.

"This collaboration and license agreement with CSL validates our belief that M230 is an exciting recombinant product candidate for potential use in autoimmune indications. It was developed using our proprietary Fc biology platform and understanding of how intravenous immunoglobulin (IVIg) works in autoimmune diseases," said Craig A. Wheeler, President and Chief Executive Officer of Momenta Pharmaceuticals. "As the global leader in immunoglobulin (Ig) therapy, CSL is the ideal development and commercialization partner for us in the area of Fc biology given their expertise in developing plasma-derived medicines and focus on creating disruptive recombinant products in the autoimmune space."

"We are delighted to announce this collaboration with Momenta, who are leaders in the Fc biology space," said Paul Perreault, CEO and Managing Director, CSL. "M230 is a very exciting prospect and offers CSL the potential to further grow and expand our long-term global leadership in helping those patients with autoimmune diseases that are treated with immunoglobulins."

Under the terms of the agreement, Momenta will grant CSL an exclusive, worldwide license to Momenta's intellectual property relating to M230. Momenta will receive a $50 million upfront license fee payment from CSL and will also be eligible for up to $550 million in contingent clinical, regulatory and commercialization milestone payments. Momenta has the option to elect a cost and profit sharing arrangement, for which Momenta would fund a proportion of global development and commercialization costs in exchange for a share of U.S. profits, and milestones and royalties outside the United States. Momenta has the option to enter into an agreement to co-promote M230 and any other collaboration product in the U.S.

The companies expect to close the transaction in the first quarter of 2017, subject to customary closing conditions including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

Conference Call Information

Momenta will host a conference call for investors today at 4:30 pm ET to discuss this important collaboration with CSL. The conference call will be webcast live and a link to the webcast may be accessed on the "Investors" section of the company's website, www.momentapharma.com. Please go to the site at least 15 minutes prior to the call to register, download, and install

any necessary software. An archived version of the webcast will be posted on the Momenta website approximately two hours after the call.

To access the call you may also dial (877) 224-9084 (domestic) or (720) 545-0022 (international) prior to the scheduled conference call time and provide the access code INSERT. A replay of the call will be available approximately two hours after the conclusion of the call. To access the replay, please dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and provide the access code INSERT.

About M230, Selective Immunomodulator of Fc Receptors (SIF3)

Antigen-autoantibody immune complexes (ICs) are a common pathogenic hallmark of many autoimmune diseases. The multiple Fc domains of ICs aggregate Fcγ receptors (FcγRs), triggering cellular activation processes that play critical roles in inflammation and tissue damage. The rational engineering of therapeutics that broadly antagonize FcγRs has been hampered by a limited understanding of the molecular determinants directing FcγR activation. Through the engineering and characterization of oligomeric Fc structures, Momenta has been able to derive novel insights into FcγR modulation and has generated a unique recombinant Fc multimer therapeutic candidate, referred to as M230, with excellent physiochemical and biological properties. Preclinical studies in animal models of autoimmune disease have shown that M230 matched potency and efficacy of intravenous immunoglobulin at significantly lower doses. M230 is currently in preclinical development and is expected to enter the clinic in 2017.

About Momenta
Momenta Pharmaceuticals is a biotechnology company specializing in the detailed structural analysis of complex drugs and is headquartered in Cambridge, MA. Momenta is applying its technology to the development of generic versions of complex drugs, biosimilar and potentially interchangeable biologics, and to the discovery and development of novel therapeutics for autoimmune indications.

To receive additional information about Momenta, please visit the website at www.momentapharma.com, which does not form a part of this press release.

About CSL
CSL (ASX:CSL) is a leading global biotherapeutics company with a dynamic portfolio of life-saving innovations, including those that treat hemophilia and immune deficiencies, as well as vaccines to prevent influenza. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL — including our two businesses CSL Behring and Seqirus – conducts business in more than 60 countries with more than 17,000 employees. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For additional information about CSL, please visit www.CSL.com.au.

Forward Looking Statement For Momenta Pharmaceuticals
Statements in this press release regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including but not limited to, statements concerning the collaboration and license agreement between CSL and Momenta Pharmaceuticals, Inc., including anticipated payments, as well as future development, manufacture, and commercialization of novel drugs under the agreement; and our and CSL's ability to successfully develop and commercialize M230. Forward-looking statements may be identified by words such as "anticipate," "believe," "continue," "could," "hope," "target," "project," "goal," "objective," "guidance," "plan," "potential," "predict," "might," "estimate," "expect," "intend," "may," "seek", "should," "will," "would," "look forward" and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including receiving clearance under the Hart-Scott-Rodino Antitrust Improvements Act and those referred to under the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 filed with the Securities and Exchange Commission, as well as other documents that may be filed by the Company from time to time with the Securities and Exchange Commission. As a result of such risks, uncertainties and factors, or the risks and factors noted below by CSL, the Company's actual results may differ materially from any future results, performance or achievements discussed in or implied by the forward-looking statements contained herein. The Company is providing the information in this press release as of this date and assumes no obligations to update the information included in this press release or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Confidential Portions of this Exhibit marked as [***] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

Forward Looking Statement for CSL

The information in this press release speaks only as of the date of this press release, and includes forward looking statements about CSL business prospects and products in research, all of which involve substantial risks and uncertainties, many of which are outside the control of, and are unknown to, CSL. You can identify these forward looking statements by the fact that they use words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "target," "may," "assume," and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. Factors that could cause actual results to differ materially include: the success of research and development activities, decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; competitive developments affecting our products; the ability to successfully market new and existing products; difficulties or delays in manufacturing; trade buying patterns and fluctuations in interest and currency exchange rates; legislation or regulations that affect product production, distribution, pricing, reimbursement or access; litigation or government investigations, and CSL's ability to protect its patents and other intellectual property. The statements being made in this presentation do not constitute an offer to sell, or solicitation of an offer to buy, any securities of CSL.

No representation, warranty or assurance (express or implied) is given or made in relation to any forward looking statement by any person (including CSL). In particular, no representation, warranty or assurance (express or implied) is given in relation to any underlying assumption or that any forward looking statement will be achieved. Actual future events may vary materially from the forward looking statements and the assumptions on which the forward looking statements are based.

Subject to any continuing obligations under applicable law or any relevant listing rules of the Australian Securities Exchange, CSL disclaims any obligation or undertaking to disseminate any updates or revisions to any forward looking statements in this press release to reflect any change in expectations in relation to any forward looking statements or any change in events, conditions or circumstances on which any such statement is based. Nothing in this press release shall under any circumstances create an implication that there has been no change in the affairs of CSL since the date of this press release.

###

MOMENTA INVESTOR CONTACT:
Sarah Carmody
Momenta Pharmaceuticals
1-617-395-5189
IR@momentapharma.com

MOMENTA MEDIA CONTACT:
Karen Sharma
MacDougall Biomedical Communications
1-781-235-3060
Momenta@macbiocom.com

CSL INVESTOR CONTACT:
Mark Dehring
CSL
+61 3 9389 3407
Mark.Dehring@CSL.com.au

CSL MEDIA CONTACT:
Natalie de Vane
CSL
1-610-878-4468
Natalie.deVane@CSLBehring.com

Exhibit 10.2

Confidential Treatment Requested by Momenta Pharmaceuticals, Inc.

CSL Limited
45 Poplar Road Parkville
Victoria 3052 Australia

T +613 9389 1911
F +613 9389 1434
www.csl.com.au

CSL™

4 January 2017

Momenta Pharmaceuticals, Inc.
675 West Kendall Street
Cambridge, MA, 02142
United States
Attention: Chief Executive Officer

Dear Sirs,

We, as the ultimate 100% shareholder of CSL Behring Recombinant Facility AG ("the Company") as of the date of this letter, confirm that it is [***] to [***] be [***] to [***] the [***] to [***] any Affiliate to whom obligations may be delegated or assigned to fulfil its obligations under the License and Option Agreement between it and Momenta Pharmaceuticals , Inc. ("Agreement")

[***] to [***] the [***] of [***] and [***] to the [***] to [***] the [***] the [***] and [***] the [***]. This guarantee is provided for a period of [***] from [***] the Agreement. [***] the [***] be [***] to [***] to [***] that [***] is [***] and [***] to [***] the [***] to [***] be [***] the [***] be [***] to [***] a [***] on [***] the [***] as [***].

You will be informed immediately in the event that circumstances change in a manner such that CSL Limited is no longer able to continue to provide such [***].

I confirm that I am authorised to provide these assurances on behalf of CSL Limited.

/s/ David Lamont

David Lamont
Chief Financial Officer

For and on behalf of CSL Limited

Exhibit 10.3

EXECUTION COPY

AMENDMENT NO. 1 TO ASSET RETURN AND TERMINATION AGREEMENT

This AMENDMENT NO. 1 TO ASSET RETURN AND TERMINATION AGREEMENT (this " Amendment "), effective as of March 20, 2017, amends that certain Asset Return and Termination Agreement, effective December 31, 2016 (the " AR&T Agreement "), by and between Momenta Pharmaceuticals, Inc., a Delaware corporation (" Momenta "), Baxalta Incorporated, a Delaware corporation (" BI "), Baxalta US Inc., a Delaware corporation (" BUSI "), and Baxalta GmbH, a Swiss corporation (" BGMBH " and, together with BI and BUSI, collectively, " Baxalta "). Capitalized terms used herein, but otherwise not defined, shall have the meaning ascribed to them in the AR & T Agreement.

RECITALS

WHEREAS, the Parties hereto desire to amend the AR&T Agreement as set forth below in accordance with Section 8.7 of the AR&T Agreement.

AGREEMENT

NOW THEREFORE, in consideration of the foregoing recitals, which are incorporated into this Amendment, the mutual agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Amendment of the AR&T Agreement . Exhibit F to the AR&T Agreement is hereby amended and restated in its entirety to read as set forth in Exhibit 1 to this Amendment.

2. No Other Changes . Except as expressly modified by this Amendment, the AR&T Agreement shall remain unchanged and in full force and effect. This Amendment shall become a part of the AR&T Agreement as if set forth in full therein, and references to the AR&T Agreement shall be to the AR&T Agreement as amended. To the extent of any conflict or inconsistency between the terms of this Amendment and the AR&T Agreement, the terms of this Amendment shall prevail.

3. Counterparts; Electronic Delivery . This Amendment may be executed in two or more counterparts, each of which may contain the signature of one or more parties hereto, but all such counterparts taken together shall constitute one and the same agreement. Signatures to this Amendment transmitted by facsimile, by email in "portable document format" (".pdf"), or by other electronic means intended to preserve the original graphic and pictorial appearance of this Amendment shall have the same effect as physical delivery of the paper document bearing original signature.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Amendment No. 1 to Asset Return and Termination Agreement as of the date first set forth above.

Momenta Pharmaceuticals, Inc.

By: /s/ Matt Ottmer
Name: Matt Ottmer
Title: Chief Operating Officer

[s *ignatures continue on following page*]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Amendment No. 1 to Asset Return and Termination Agreement as of the date first set forth above.

Baxalta Incorporated

By: /s/ Jeffrey Prowda
Name: Jeffrey Prowda
Title: Assistant Secretary

Baxalta US Inc.

By: /s/ Jeffrey Prowda
Name: Jeffrey Prowda
Title: Assistant Secretary

[signatures continue on following page]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Amendment No. 1 to Asset Return and Termination Agreement as of the date first set forth above.

Baxalta GmbH

By: /s/ Mario Nespoli
Name: Mario Nespoli
Title: Director Strategic Sourcing & Procurement CMO

Signature Page to Amendment No. 1 to Asset Return and Termination Agreement

Exhibit 1

Amended and Restated Exhibit F to Asset Return and Termination Agreement

Module	Major Sections	Regulatory Services to be Performed by Baxalta in Accordance with Section 4.2
[***]	[***]	[***]

* * * * * * * * * *

Exhibit 1 to Amendment No. 1 to Asset Return and Termination Agreement

Confidential Portions of this Exhibit marked as [***] have been omitted pursuant to a request for confidential treatment and have been filed separately with the Securities and Exchange Commission.

Exhibit 10.4

MOMENTA PHARMACEUTICALS, INC.
EQUITY AWARD RETIREMENT POLICY

1. Purpose. The purpose of this equity award retirement policy (this "*Policy*") is to provide for the treatment of Awards held by Eligible Participants upon their qualifying retirement from the Company, notwithstanding any provision of the Plan or any agreement governing an Award to the contrary. This Policy is effective as of December 14, 2016 (the "*Effective Date*").

2. Definitions. As used in this Policy, the following terms shall have the meanings set forth below:

(a) "*Award*" means an Option or RSU.

(b) "*Board*" means the Board of Directors of the Company.

(c) "*Company*" means Momenta Pharmaceuticals, Inc.

(d) "*Compensation Committee*" means the Compensation Committee of the Board.

(e) "*Cut-Off Date*" means January 1, 1972.

(f) "*Eligible Participant*" means any (i) employee of the Company and its subsidiaries or (ii) non-employee Board member.

(g) "*Eligible Retirement Date*" means the date on which (i) an Eligible Participant attains a minimum age of fifty-five (55) years and a minimum of five (5) years of full-time employment with the Company and its subsidiaries or service as a Board member, as measured from the Eligible Participant's hire date or commencement of service as a Board member and (ii) the sum of the Eligible Participant's age and number of years of such employment or service equals or exceeds sixty-five (65) years.

(h) "*Option*" means an option to purchase shares of the Company's common stock granted or that may be granted to an Eligible Participant under the Plan.

(i) "*Plan*" means the Momenta Pharmaceuticals, Inc. 2013 Incentive Award Plan, the Momenta Pharmaceuticals, Inc. 2004 Stock Incentive Plan and, to the extent applicable, any future or successor equity compensation plan of the Company, in each case as applicable to an Award and as amended or restated from time to time.

(j) "*Retirement Date*" means the last date, due to retirement on or after an Eligible Participant's Eligible Retirement Date, of the Eligible Participant's (i) employment if the Eligible Participant is an employee or (ii) service to the Company and its subsidiaries as a Board member if the Eligible Participant is a non-employee Board member.

(k) "*Retirement Vesting Period*" means the one year period following the Retirement Date.

(l) "*RSU*" means a restricted stock unit denominated in shares of the Company's common stock granted or that may be granted to an Eligible Participant under the Plan subject to service-based (but not performance-based) vesting conditions.

3. Treatment of Awards Upon Retirement. Except as otherwise provided in this Policy, including in Section 4, following an Eligible Participant's Retirement Date:

(a) The Eligible Participant's Awards that are outstanding as of the Eligible Participant's Retirement Date will continue to vest and, if applicable, become exercisable during the Eligible Participant's

Retirement Vesting Period as if the Eligible Participant had remained continuously in service as an employee of the Company and its subsidiaries or a non-employee Board member, as applicable, during the Eligible Participant's Retirement Vesting Period; and

(b) The Eligible Participant will have until the first anniversary of the Retirement Date to exercise any vested Options, provided that (i) if an Option (or portion thereof) becomes first exercisable within the ninety (90) days preceding the first anniversary of the Retirement Date, then the Eligible Participant will have ninety (90) days following the date that the Option (or portion thereof) becomes first exercisable to exercise such Option (or portion thereof) and (ii) no Option may be exercised following the date upon which the Option would have become unexercisable, including in connection with a corporate transaction or event, had the Eligible Participant remained continuously in service as an employee or non-employee Board member, as applicable, with the Company and its subsidiaries.

4. Limitations; Conditions . The provisions of Section 3 are subject to the following limitations and conditions unless the Committee or the Board otherwise determines:

(a) This Policy will not apply to any Option outstanding as of the Effective Date that is an "incentive stock option" within the meaning of Section 422 of the Internal Revenue Code and is held by an Eligible Participant born before the Cut-Off Date if, within twenty-eight (28) calendar days following the Effective Date, the Eligible Participant holding such Option declines the benefits of this Policy in a form provided by the Company.

(b) An Eligible Participant must provide the Company with written notice of the Eligible Participant's intention to retire at least thirty (30) days but no more than sixty (60) days prior to the Eligible Participant's Retirement Date in order to receive the benefit of this Policy, except that an Eligible Participant who retires within forty-five (45) days following the Effective Date must provide such notice no later than the Eligible Participant's Retirement Date. Such written notice must be in a form reasonably acceptable to the Company and include a representation of the Eligible Participant that the Eligible Participant is terminating from the Company for retirement purposes and has not accepted, and does not plan to accept, a full-time position at another employer in the biotechnology or pharmaceutical industries. For clarity, post-retirement services as a member of a board of directors or similar board or committee shall not disqualify an Eligible Participant from this Policy.

(c) The benefits provided under Section 3 are conditioned upon an Eligible Participant's continued compliance with any non-competition, non-solicitation, confidentiality or other restrictive covenants with the Company and may be subject to any additional limitations, restrictions, modifications and/or conditions (if any) as the Compensation Committee or the Board may from time to time determine. Any such limitation, restriction, modification or condition must specifically reference this Policy.

(d) If an Eligible Participant continuously provides services to the Company and its subsidiaries following retirement, then the Administrator will determine the effect of such continued service on the provisions of Section 3 and the Eligible Participant's benefits under this Policy.

5. Discretion . The Compensation Committee or the Board may, in its discretion and at any time or from time to time, including for the avoidance of doubt following an Eligible Participant's Retirement Date, determine that this Policy does not apply to any or all Awards held by an Eligible Participant or terminate, amend or modify this Policy. Any such determination, termination, amendment or modification must specifically reference this Policy.

6. Interpretation . The Compensation Committee, the Board or the designee of either may interpret the terms and application of this Policy, and in such capacity is referred to herein as the " Administrator ." All interpretations of the Administrator will be conclusive and binding on all persons. In the absence of a contrary designation, the

Company's Senior Vice President, Human Resources will be the Administrator. Notwithstanding the foregoing, only the Board or Compensation Committee will administer this Policy and be the Administrator with respect to Senior Vice Presidents and individuals who are subject to Section 16 of the Securities Exchange Act of 1934, as amended.

7. Incorporation of Equity Plan . This Policy is established under and subject to the terms of the Plan. Notwithstanding the foregoing, if there is a conflict between the terms of the Plan and this Policy, the terms of this Policy will control.

* * * * *

Exhibit 31.1

CERTIFICATION

I, Craig A. Wheeler, 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: May 5, 2017

/s/ Craig A. Wheeler

Craig A. Wheeler

President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Scott M. Storer, 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: May 5, 2017

/s/ Scott M. Storer

Scott M. Storer

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 March 31, 2017 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 Scott M. Storer, 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: May 5, 2017

/s/ Craig A. Wheeler

Craig A. Wheeler

President and Chief Executive Officer

Dated: May 5, 2017

/s/ Scott M. Storer

Scott M. Storer

Senior Vice President and Chief Financial Officer