UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM	10-Q
Mark One) ⊠ QUARTERLY REPORT PURSUANT TO SECTION 13 O 1934	R 15(d) OF THE SECURITIES EXCHANGE ACT OF
For the quarterly period en	ded September 30, 2014
OR	
☐ TRANSITION REPORT PURSUANT TO SECTION 13 C 1934	R 15(d) OF THE SECURITIES EXCHANGE ACT OF
For the transition period from	to
Commission file nu	mber: 001-35409
Merrimack Phari (Exact name of registrant as Delaware (State or other jurisdiction of incorporation or organization)	•
One Kendall Square, Suite B7201	
Cambridge, MA (Address of principal executive offices)	02139 (Zip Code)
(617) 441 (Registrant's telephone num	
Indicate by check mark whether the registrant (1) has filed all reports 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 ($\S23$) period that the registrant was required to submit and post such files). Yes \square	

3	mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer arge accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the large accelerated filer.	1 0 1 5	7.
Large accelerated filer		Accelerated filer	\boxtimes
Non-accelerated filer	\square (Do not check if a smaller reporting company)	Smaller reporting company	
Indicate by check	mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).	Yes □ No ⊠	
As of October 31	2014, there were 105,884,138 shares of Common Stock, $\$0.01$ par value per share, outstanding.		
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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- · our plans to develop and commercialize our most advanced product candidates and companion diagnostics;
- our ongoing and planned discovery programs, preclinical studies and clinical trials;
- the timing of the completion of our clinical trials and the availability of results from such trials;
- our collaborations with Baxter and PharmaEngine related to MM-398;
- our collaboration with Sanofi related to MM-121, including the termination of such collaboration;
- our ability to establish and maintain additional collaborations;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of our products;
- our intellectual property position;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the potential advantages of our Network Biology approach to drug research and development;
- the potential use of our Network Biology approach in fields other than oncology; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in Part II, Item 1A. Risk Factors, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments that we may enter into or make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements.

Merrimack Pharmaceuticals, Inc. Condensed Consolidated Balance Sheets

(in thousands, except par value) (unaudited)	Sep	tember 30, 2014	De	cember 31, 2013
Assets				
Current assets:				
Cash and cash equivalents	\$	100,323	\$	65,086
Available-for-sale securities		53,356		90,116
Restricted cash		101		101
Accounts receivable		2,568		5,857
Prepaid expenses and other current assets		5,795		5,484
Total current assets		162,143		166,644
Restricted cash		584		584
Property and equipment, net		14,313		13,364
Other assets		152		175
Intangible assets, net		1,605		1,845
In-process research and development		6,200		6,200
Goodwill		3,605	_	3,605
Total assets	\$	188,602	\$	192,417
Liabilities, Non-Controlling Interest and Stockholders' Deficit Current liabilities:				
Accounts payable, accrued expenses and other	\$	35,989	\$	38,814
Deferred revenues		68,737		9,336
Deferred rent		1,282		1,336
Long-term debt, current portion		15,227		8,248
Total current liabilities	_	121,235	_	57,734
Deferred revenues, net of current portion		56,264		66,139
Deferred rent, net of current portion		5,710		6,538
Deferred tax incentives, net of current portion		629		507
Long-term debt, net of current portion		103,428		103,427
Accrued interest		1,200		1,200
Total liabilities	_	288,466	_	235,545
Commitments and contingencies (Note 10)				
Non-controlling interest		(150)		337
Stockholders' deficit:				
Preferred stock, \$0.01 par value: 10,000 shares authorized at September 30, 2014 and December 31, 2013; no				
shares issued or outstanding at September 30, 2014 or December 31, 2013 Common stock, \$0.01 par value: 200,000 shares authorized at September 30, 2014 and December 31, 2013;				_
105,655 and 102,523 shares issued and outstanding at September 30, 2014 and December 31, 2013,		1,057		1,025
Additional paid-in capital		545,112		527,779
Accumulated other comprehensive loss		(43)		(24)
Accumulated deficit		(645,840)		(572,245)
	_		_	<u>· · · · · · · · · · · · · · · · · · · </u>
Total stockholders' deficit		(99,714)		(43,465)
Total liabilities, non-controlling interest and stockholders' deficit	\$	188,602	\$	192,417

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

Merrimack Pharmaceuticals, Inc. Condensed Consolidated Statements of Comprehensive Loss

	Three mor Septem		Nine mon Septem	
(in thousands, except per share amounts) (unaudited)	2014	2013	2014	2013
Collaboration revenues	\$ 28,002	\$ 6,856	\$ 68,851	\$ 39,963
Operating expenses:				
Research and development	43,632	37,630	107,751	117,084
General and administrative	8,095	5,150	22,240	15,177
Total operating expenses	51,727	42,780	129,991	132,261
Loss from operations	(23,725)	(35,924)	(61,140)	(92,298)
Other income and expenses				
Interest income	7	36	62	123
Interest expense	(4,585)	(3,946)	(13,666)	(6,459)
Other, net	265	71	662	297
Net loss	(28,038)	(39,763)	(74,082)	(98,337)
Less net loss attributable to non-controlling interest	(137)	(132)	(487)	(471)
Net loss attributable to Merrimack Pharmaceuticals, Inc.	\$ (27,901)	\$ (39,631)	\$ (73,595)	\$ (97,866)
Other comprehensive (loss) income:				
Unrealized (loss) gain on available-for-sale securities	(40)	(11)	(19)	22
Other comprehensive (loss) income	(40)	(11)	(19)	22
Comprehensive loss	\$ (27,941)	\$ (39,642)	\$ (73,614)	\$ (97,844)
Net loss per share available to common stockholders—basic and diluted	\$ (0.27)	\$ (0.39)	\$ (0.71)	\$ (1.00)
Weighted-average common shares used in computing net loss per share available to common stockholders—basic and diluted	104,871	101,155	103,863	97,754

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

Merrimack Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

(in thousands)	Nine months ended Septemb		tember 30,	
(in thousands) (unaudited)		2014		2013
Cash flows from operating activities				
Net loss	\$	(74,082)	\$	(98,337)
Adjustments to reconcile net loss to net cash used in operating activities				
Non-cash interest expense		6,393		2,341
Depreciation and amortization		2,811		1,926
Stock-based compensation		9,941		7,953
Other non-cash items		_		810
Changes in operating assets and liabilities		400		(4 EDE)
Purchased premiums and interest on available-for-sale securities		432		(1,535)
Accounts receivable		4,130		432
Accounts payable, accrued expenses and other		(2,077)		19,741
Deferred revenues		49,526		(4,738)
Other assets and liabilities, net		(197)		3,657
Net cash used in operating activities		(3,123)		(67,750)
Cash flows from investing activities				
Purchases of available-for-sale securities		(70,934)		(78,699)
Proceeds from maturities of available-for-sale securities		106,733		74,140
Purchases of property and equipment		(4,714)		(9,061)
Other investing activities, net				(56)
Net cash provided by (used in) investing activities		31,085		(13,676)
Cash flows from financing activities				
Proceeds from exercise of common stock options and warrants		6,581		28,271
Proceeds from convertible notes issued by majority owned subsidiary, net of issuance costs		700		274
Proceeds from issuance of convertible senior notes, net of issuance costs		_		120,621
Payments of dividends on Series B convertible preferred stock		(7)		(3)
Other financing activities, net		1		
Net cash provided by financing activities		7,275		149,163
Net increase in cash and cash equivalents		35,237		67,737
Cash and cash equivalents, beginning of period		65,086		37,714
	\$	100,323	\$	105,451
Cash and cash equivalents, end of period	D.	100,323	Þ	103,431
Non-cash investing and financing activities				
Issuance of derivative liability		88		35
Property and equipment in accounts payable and accrued expenses		653		1,761
Disposal of fully depreciated assets		1,598		136
Receivables related to stock option exercises		841		_
Reclassification of deferred financing costs to issuance costs				278
Value of equity premium on convertible senior notes, net of issuance costs, classified in Stockholders' Deficit		_		51,876
Supplemental disclosure of cash flows				_
Cash paid for interest	\$	8,806	\$	2,849

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

Merrimack Pharmaceuticals, Inc. Notes to Condensed Consolidated Financial Statements (unaudited)

1. Nature of the Business

Merrimack Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines consisting of novel therapeutics paired with companion diagnostics for the treatment of cancer. The Company has six novel therapeutic oncology candidates in clinical development (MM-398, MM-121, MM-111, MM-302, MM-151 and MM-141), multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines. The Company also has an agreement to utilize its manufacturing expertise to develop, manufacture and exclusively supply bulk drug to a third party, who will in turn process the drug into a finished product and commercialize it globally. The Company's discovery and development efforts are driven by Network Biology, which is its proprietary systems biology-based approach to biomedical research. The Company was incorporated in the Commonwealth of Massachusetts in 1993 and reincorporated in the State of Delaware in October 2010.

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including, but not limited to, its ability to secure additional capital to fund operations, success of clinical trials, development by competitors of new technological innovations, dependence on collaborative arrangements, protection of proprietary technology, compliance with government regulations and dependence on key personnel. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, infrastructure and extensive compliance reporting capabilities.

The Company has incurred significant losses and has not generated revenue from commercial sales. The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business.

As of September 30, 2014, the Company had unrestricted cash and cash equivalents and available-for-sale securities of \$153.7 million. The Company expects that its existing unrestricted cash and cash equivalents and available-for-sale securities as of September 30, 2014 and anticipated cost sharing reimbursements under its license and collaboration agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively "Baxter") related to MM-398 will enable the Company to fund operations into the second half of 2015.

The Company may seek additional funding through public or private debt or equity financings, or through existing or new collaboration arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into additional collaborative arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. Arrangements with collaborators or others may require the Company to relinquish rights to certain of its technologies or product candidates. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs or commercialization efforts, which could adversely affect its business prospects.

2. Summary of Significant Accounting Policies

Significant accounting policies followed by the Company in the preparation of its condensed consolidated financial statements are as follows:

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements as of September 30, 2014, and for the three and nine months ended September 30, 2014 and 2013, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and generally accepted accounting principles in the United States of America ("GAAP") for condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed with the SEC on March 4, 2014.

The information presented in the condensed consolidated financial statements and related notes as of September 30, 2014, and for the three and nine months ended September 30, 2014 and 2013, is unaudited. The December 31, 2013 condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three and nine months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2014, or any future period.

On September 23, 2014, the Company merged its wholly owned subsidiary, Merrimack Pharmaceuticals (Bermuda) Ltd. ("Merrimack Bermuda"), with and into the Company, with the Company being the surviving corporation (the "Merger"). These condensed consolidated financial statements include the consolidated accounts of Merrimack Bermuda prior to the Merger.

These condensed consolidated financial statements also include the accounts of the Company and its majority owned subsidiary, Silver Creek Pharmaceuticals, Inc. ("Silver Creek"). All intercompany transactions and balances have been eliminated in consolidation.

The Company's ownership of Silver Creek was 64% as of September 30, 2014 and December 31, 2013. The consolidated financial statement activity related to Silver Creek was as follows:

(in thousands)	Non-Contr	olling Interest
Balance at December 31, 2013	\$	337
Net loss attributable to Silver Creek		(487)
Balance at September 30, 2014	\$	(150)
(in thousands)	Non-Contr	olling Interest
(in thousands) Balance at December 31, 2012	Non-Contr \$	olling Interest 97
		U

In April 2014, Silver Creek named a new Chief Executive Officer and made changes to its board of directors. The Company remains the primary beneficiary of Silver Creek, so these changes to Silver Creek's management and directors did not effect a change on the consolidation of Silver Creek for financial reporting purposes.

Use of Estimates

GAAP requires the Company's management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. The Company bases estimates and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. The most significant estimates in these condensed consolidated financial statements include revenue recognition, including the estimated percentage of billable expenses in any particular budget period, periods of meaningful use of licensed products, estimates used in accounting for revenue separability, accounting for revenue period of substantial involvement and recognition, useful lives with respect to long-lived assets and intangibles, accounting for stock-based compensation, contingencies, intangible assets, goodwill, in-process research and development, derivative liability, valuation of convertible debt, tax valuation reserves and accrued expenses, including clinical research costs. The Company's actual results may differ from these estimates under different assumptions or conditions. The Company evaluates its estimates on an ongoing basis. Changes in estimates are reflected in reported results in the period in which they become known by the Company's management.

Available-for-Sale Securities

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months as available-for-sale. Available-for-sale securities may consist of U.S. government agencies securities, commercial paper, corporate notes and bonds and certificates of deposit, which are maintained by an investment manager. Available-for-sale securities are carried at fair value, with the unrealized gains and losses included in other comprehensive (loss) income as a component of stockholders' deficit until realized. Realized gains and losses are recognized in interest income. Any premium or discount arising at purchase is amortized and/or accreted to interest income. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities during the three and nine months ended September 30, 2014 or 2013.

Available-for-sale securities, all of which have maturities of twelve months or less, as of September 30, 2014 consisted of the following:

	Amortized Cost	Unrealized Losses	Fair Value
		(in thousands)	
September 30, 2014:			
Commercial paper	\$ 3,000	\$ —	\$ 3,000
Corporate debt securities	50,400	(44)	50,356
Total	\$ 53,400	\$ (44)	\$53,356

The aggregate fair value of securities held by the Company in an unrealized loss position for less than 12 months as of September 30, 2014 was \$50.4 million, which consisted of several corporate debt securities comprising the total balance. To determine whether an other-than-temporary impairment exists for securities with significant unrealized losses, the Company performs an analysis to assess whether it intends to sell, or whether it would more likely than not be required to sell, the security before the expected recovery of the amortized cost basis. Where the Company intends to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full

amount of the unrealized loss is recognized on the statement of comprehensive income (loss) as an other-than-temporary impairment charge. When this is not the case, the Company performs additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified when the Company does not expect to receive cash flows, based on using a single best estimate, sufficient to recover the amortized cost basis of a security, and the amount of the loss is recognized in other income (expense).

The Company does not intend to sell, and it is not more likely than not that the Company will be required to sell, the above investments before the recovery of their amortized cost bases, which may occur upon maturity. The Company determined that there was no material change in the credit risk of the above investments. As a result, the Company determined it did not hold any investments with an other-than-temporary-impairment as of September 30, 2014.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents, available-for-sale securities and accounts receivable. The Company places its cash deposits in accredited financial institutions and, therefore, the Company's management believes these funds are subject to minimal credit risk. The Company invests cash equivalents and available-for-sale securities in money market funds, U.S. government agencies securities and various corporate debt securities. Credit risk in these securities is reduced as a result of the Company's investment policy to limit the amount invested in any one issue or any single issuer and to only invest in high credit quality securities. The Company has no significant off-balance sheet concentrations of credit risk such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Revenue Recognition

The Company enters into biopharmaceutical product development agreements with collaborative partners for the research and development of therapeutic and diagnostic products. The terms of the agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties or profit-sharing on any product sales derived from collaborations. These multiple element arrangements are analyzed to determine whether the deliverables can be separated or whether they must be accounted for as a single unit of accounting.

In January 2011, the Company adopted authoritative guidance on revenue recognition for multiple element arrangements. This guidance, which applies to multiple element arrangements entered into or materially modified on or after January 1, 2011, separates and allocates consideration in a multiple element arrangement according to the relative selling price of each deliverable. The fair value of deliverables under the arrangement may be derived using a best estimate of selling price if vendor specific objective evidence and third-party evidence are not available. Deliverables under the arrangement will be separate units of accounting provided that a delivered item has value to the customer on a stand-alone basis and if the arrangement does not include a general right of return relative to the delivered item and delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor.

On September 23, 2014, the Company entered into a license and collaboration agreement with Baxter, which was evaluated under the accounting guidance for multiple element arrangements. See Note 4, "License and Collaboration Agreements," for additional information.

The Company's license and collaboration agreements executed prior to January 1, 2011 continue to be accounted for under previously issued revenue recognition guidance for multiple element arrangements. The Company recognized upfront license payments as revenue upon delivery of the license only if the license had stand-alone value and the fair value of the undelivered performance obligations could be determined. If the fair value of the undelivered performance obligations could be determined,

such obligations were accounted for separately as the obligations were fulfilled. If the license was considered to either not have stand-alone value or have stand-alone value but the fair value of any of the undelivered performance obligations could not be determined, the arrangement was accounted for as a single unit of accounting and the license payments and payments for performance obligations were recognized as revenue over the estimated period of when the performance obligations would be performed.

Whenever the Company determined that an arrangement should be accounted for as a single unit of accounting, it determined the period over which the performance obligations would be performed and revenue would be recognized. If the Company could not reasonably estimate the timing and the level of effort to complete its performance obligations under the arrangement, then revenue under the arrangement was recognized on a straight-line basis over the period the Company expected to complete its performance obligations, which is reassessed at each subsequent reporting period.

The Company's collaboration agreements may include additional payments upon the achievement of performance-based milestones. As milestones are achieved, a portion of the milestone payment, equal to the percentage of the total time that the Company has performed the performance obligations to date over the total estimated time to complete the performance obligations, multiplied by the amount of the milestone payment, will be recognized as revenue upon achievement of such milestone. The remaining portion of the milestone will be recognized over the remaining performance period. Milestones that are tied to regulatory approvals are not considered probable of being achieved until such approval is received. Milestones tied to counterparty performance are not included in the Company's revenue model until the performance conditions are met.

Royalty revenue will be recognized upon the sale of the related products provided the Company has no remaining performance obligations under the arrangement.

Stock-Based Compensation

The Company expenses the fair value of employee stock options over the vesting period. Compensation expense is measured using the fair value of the award at the grant date, net of estimated forfeitures, and is adjusted annually to reflect actual forfeitures. The fair value of each stock-based award is estimated using the Black-Scholes option valuation model and is expensed straight-line over the vesting period.

The Company records stock options issued to non-employees at fair value, periodically remeasures to reflect the current fair value at each reporting period, and recognizes expense over the related service period. When applicable, these equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

Other Income and Expense

The Company records gains and losses on the recognition of federal and state sponsored tax incentives and other one-time income or expense-related items in other income (expense).

In May 2014, the Company received an award of \$0.6 million of tax incentives from the Massachusetts Life Sciences Center, which allows the Company to monetize approximately \$0.6 million of state research and development tax credits. In exchange for these incentives, the Company pledged to hire an incremental 31 employees and to maintain the additional headcount through at least December 31, 2018. Failure to do so could result in the Company being required to repay some or all of these incentives. The Company achieved this pledge in the third quarter of 2014 and will amortize the benefit of this monetization on a straight-line basis over the five-year performance period.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board ("FASB") issued guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss or a tax credit carryforward exists. This guidance was effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

In May 2014, the FASB issued guidance 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. This guidance will be effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is not permitted. The Company is currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on the consolidated financial statements.

In August 2014, the FASB issued guidance outlining management's responsibility to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and providing guidance on determining when and how to disclose going concern uncertainties in the financial statements. This guidance will be effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. The Company does not anticipate a material impact to the Company's consolidated financial statements as a result of this change.

3. Net Loss Per Common Share

Basic net loss per share is calculated by dividing the net loss available to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss available to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method.

As discussed in Note 7, "Borrowings," in July 2013, the Company issued \$125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020 (the "Notes") in an underwritten public offering. Upon any conversion of the Notes while the Company has indebtedness outstanding under the Loan and Security Agreement (the "Loan Agreement") with Hercules Technology Growth Capital, Inc. ("Hercules"), the Notes will be settled in shares of the Company's common stock. Following the repayment and satisfaction in full of the Company's obligations to Hercules under the Loan Agreement, upon any conversion of the Notes, the Notes may be settled, at the Company's election, in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock.

For purposes of calculating the maximum dilutive impact, it is presumed that the conversion premium will be settled in common stock, inclusive of a contractual make-whole provision resulting from a fundamental change, and the resulting potential common shares included in diluted earnings per share if the effect is more dilutive. For purposes of this calculation, conversion of the Notes, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. The stock options, warrants and conversion premium on the Notes are excluded from the calculation of diluted loss per share because the net loss for the three and nine months ended September 30, 2014 and 2013 causes such securities to be anti-dilutive. The potential dilutive effect of these securities is shown in the chart below:

	As of Sept	ember 30,
(in thousands)	2014	2013
Options to purchase common stock	20,547	20,355
Common stock warrants	2,402	2,777
Conversion premium on the Notes	25,000	25,000

4. License and Collaboration Agreements

Baxter

On September 23, 2014, the Company and Baxter entered into a license and collaboration agreement (the "Baxter Agreement") for the development and commercialization of MM-398 outside of the United States and Taiwan (the "Licensed Territory"). As part of the Baxter Agreement, the Company granted Baxter an exclusive, royalty-bearing right and license under the Company's patent rights and know-how to develop and commercialize MM-398 in the Licensed Territory. Baxter is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercializing MM-398 in the Licensed Territory. A joint steering committee comprised of an equal number of representatives from each of Baxter and the Company is responsible for approving changes to the global development plan for MM-398, including all budgets, and overseeing the parties' development and commercialization activities with respect to MM-398. Unless otherwise agreed, the Company will be responsible for conducting all clinical trials contemplated by the global development plan for MM-398 and manufacturing all clinical material needed for such trials.

Under the terms of the Baxter Agreement, the Company received a \$100.0 million upfront, nonrefundable cash payment. In addition, the Company is eligible to receive from Baxter (i) up to an aggregate of \$100.0 million upon the achievement of specified research and development milestones, (ii) up to an aggregate of \$520.0 million upon the achievement of specified regulatory milestones and (iii) up to an aggregate of \$250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxter Agreement, the Company will bear up to the first \$98.8 million of costs related to the development of MM-398 for pancreatic cancer patients who have not previously received gemcitabine; however, the Company expects most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. The Company and Baxter will share equally all other clinical trial costs contemplated by the global development plan. The Company is also entitled to tiered, escalating royalties ranging from sub-teen double-digits to low twenties percentages of net sales of MM-398 in the Licensed Territory.

The Company and Baxter expect to enter into a commercial supply agreement pursuant to which the Company will supply MM-398 bulk drug substance to Baxter and, at Baxter's option, may manage fill and finish activities to be conducted by a third party contract manufacturer for Baxter. Baxter also has the option to manufacture MM-398 itself, in which case the Company will perform a technology transfer of its manufacturing process to Baxter.

Under the Baxter Agreement, the Company granted Baxter a right of first negotiation to obtain a license to develop and commercialize MM-111, MM-141 and MM-302 outside of the United States.

If not terminated earlier by either party, the Baxter Agreement will expire upon expiration of all royalty and other payment obligations of Baxter under the Baxter Agreement. Either party may terminate the Baxter Agreement in the event of an uncured material breach by the other party. Baxter may also terminate the Baxter Agreement on a product-by-product, country-by-country or sub-territory-by-sub-territory basis or in its entirety, for its convenience, upon 180 days' prior written notice. In addition, the Company may terminate the Baxter Agreement if Baxter challenges or supports any challenge of the Company's licensed patent rights.

At the inception of the collaboration, the Company identified the following deliverables as part of the Baxter Agreement: (i) license to develop and commercialize MM-398 in Baxter's territories, (ii) discovery, research, development and manufacturing services required to complete ongoing clinical trials related to MM-398, (iii) discovery, research, development and manufacturing services needed to complete future clinical trials in further indications related to MM-398, (iv) the option to perform a technology transfer of the Company's manufacturing process related to the production of MM-398 to Baxter and (v) participation on the joint steering committee.

The Company concluded that none of the deliverables identified at the inception of the collaboration has standalone value from the other undelivered elements. As such, all deliverables represent a single unit of accounting.

The Company has determined that the collaboration represents a services agreement and as such has estimated the level of effort expected to be incurred as a result of providing the identified deliverables. The Company will recognize revenue from the upfront payment, non-substantive milestone payments and payments related to discovery, research, development and technology transfer services based on proportional performance as effort is incurred over the expected services period.

Research, development and regulatory milestones that are considered substantive on the basis of the contingent nature of the milestone will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All sales milestones will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

During the three and nine months ended September 30, 2014, the Company recognized no revenue associated with the Baxter Agreement. As of September 30, 2014, the Company had \$100.0 million of deferred revenue related to the Baxter Agreement, \$47.5 million of which is classified as current, with the remainder classified as non-current in the condensed consolidated balance sheets based upon the Company's estimate of revenue that will be recognized within the next twelve months.

Sanofi

On September 30, 2009, the Company and Sanofi entered into a license and collaboration agreement (the "Sanofi Agreement") for the development and commercialization of MM-121. The Sanofi Agreement became effective on November 10, 2009, and Sanofi paid the Company a nonrefundable, noncreditable upfront license fee of \$60.0 million. From the effective date of the Sanofi Agreement through September 30, 2014, the Company has received total milestone payments of \$25.0 million pursuant to the Sanofi Agreement. Under the Sanofi Agreement, Sanofi is responsible for all MM-121 development and manufacturing costs. Sanofi reimburses the Company for direct costs incurred in both development and manufacturing and compensates the Company for its internal development efforts based on a full time equivalent rate.

On June 17, 2014, the Company and Sanofi agreed to terminate the Sanofi Agreement effective December 17, 2014, although the Company has the right to accelerate such termination date. In connection with the agreement to terminate the Sanofi Agreement, among other things, Sanofi transferred ownership of the investigational new drug application for MM-121 back to the Company in July 2014, and the Company waived Sanofi's obligation to reimburse the Company for MM-121 development costs incurred after the effective termination date. Effective upon the termination of the Sanofi Agreement, the Company will not be entitled to receive any additional fees, milestone payments or reimbursements from the collaboration.

The Company recognizes cost reimbursements for MM-121 development services within the period they are incurred and billable. Billable expenses are identified during each specified budget period. For the three and nine months ended September 30, 2014, this specified budget period was prospectively determined to end December 17, 2014, although the specified allowable budget expense was not changed. In the event that total development services expense incurred and expected to be incurred during the same period exceed the total contractually allowed billable amount for development services during that period, the Company recognizes only a percentage of the development services incurred as revenue during that period. This percentage is calculated as total development services expense incurred during the specified budget period divided by the sum of total development services expense incurred plus estimated development services expense to be incurred during the specified period, multiplied by the total contractually allowed billable amount for development services during the specified period, less development services revenue previously recognized within the specified period.

At the inception of the collaboration, the Company determined that the license, the right to future technology, back-up compounds, participation on steering committees and manufacturing services performance obligations comprising the Sanofi Agreement represented a single unit of accounting. As the Company cannot reasonably estimate its level of effort over the collaboration, the Company recognizes revenue from the upfront payment, milestone payment and manufacturing services payments using the contingency-adjusted performance model over the expected development period, which was initially estimated at 12 years from the effective date of the Sanofi Agreement.

As a result of the Company and Sanofi agreeing to terminate the Sanofi Agreement, the development period was revised to end as of December 17, 2014. Accordingly, the balance of the deferred revenue remaining on April 1, 2014 is being recognized prospectively on a straight-line basis over the remaining development period, estimated to end on December 17, 2014, in accordance with current generally accepted principles on revenue recognition.

During the three and nine months ended September 30, 2014 and 2013, the Company recognized revenue based on the following components of the Sanofi Agreement:

	Three mon	Three months ended		ths ended
	Septeml	ber 30,	Septen	ıber 30,
(in thousands)	2014	2013	2014	2013
Upfront payment	\$13,415	\$1,250	\$27,933	\$ 3,750
Milestone payments	5,590	521	11,639	1,562
Development services	2,953	4,521	16,694	30,794
Manufacturing services and other	6,044	564	12,585	3,304
Total	\$28,002	\$6,856	\$68,851	\$39,410

The Company performs development services for which revenue is recognized under the Sanofi Agreement in accordance with the specified budget period. Additionally, for the nine months ended September 30, 2014, there is approximately \$5.8 million of increased revenue related to the Company receiving budget approval for expenses incurred prior to December 31, 2013.

As of September 30, 2014 and December 31, 2013, the Company maintained the following assets and liabilities related to the Sanofi Agreement:

(in thousands)	September 30, 2014	December 31, 2013
Accounts receivable, billed	\$ 1,387	\$ 2,357
Accounts receivable, unbilled	302	3,417
Deferred revenue	21,236	73,392

PharmaEngine, Inc.

On May 5, 2011, the Company and PharmaEngine, Inc. ("PharmaEngine") entered into an assignment, sublicense and collaboration agreement (the "PharmaEngine Agreement") under which the Company reacquired rights in Europe and certain countries in Asia to MM-398. In exchange, the Company agreed to pay PharmaEngine a nonrefundable, noncreditable upfront payment of \$10.0 million and up to an additional \$80.0 million in aggregate development and regulatory milestones and \$130.0 million in aggregate sales milestones. During the first quarter of 2012, the Company paid a development milestone of \$5.0 million under the PharmaEngine Agreement in connection with dosing the first patient in a Phase 3 clinical trial of MM-398 in pancreatic cancer. PharmaEngine is also entitled to tiered royalties on net sales of MM-398 in Europe and certain countries in Asia. PharmaEngine is not responsible for any future development costs of MM-398 except those required specifically for regulatory approval in Taiwan.

On September 22, 2014, the Company amended the PharmaEngine Agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that the Company is required to pay to PharmaEngine. As a result of this amendment, the Company made a \$7.0 million milestone payment to PharmaEngine in September 2014. Additionally, as a result of this amendment, a previously contingent \$5.0 million milestone payment is now payable to PharmaEngine upon the earlier of either the U.S Food and Drug Administration's acceptance of a new drug application for MM-398 or April 30, 2015. Prior to the amendment of the PharmaEngine Agreement, this milestone payment was contingent upon the award of certain specified regulatory designations. These milestone payments were recognized as research and development expense during the three months ended September 30, 2014.

During the three months ended September 30, 2014 and 2013, the Company recognized research and development expenses of \$12.4 million and \$0.5 million, respectively, and during the nine months ended September 30, 2014 and 2013, the Company recognized research and development expenses of \$12.5 million and \$1.0 million, respectively, related to the PharmaEngine Agreement.

Actavis

On November 25, 2013, the Company and Watson Laboratories, Inc. ("Actavis") entered into a development, license and supply agreement (the "Actavis Agreement") pursuant to which the Company will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection (the "Initial Product") to Actavis. Under the Actavis Agreement, Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the Actavis Agreement, the Company has also agreed to develop additional products for Actavis in the future, the identities of which will be mutually agreed upon. The Company is eligible to receive up to \$15.5 million under the Actavis Agreement, of which \$2.9 million has been received through September 30, 2014, with the remainder relating to development funding and development, regulatory and commercial milestone payments related to the Initial Product. The Company will also receive a double digit percentage of net profits on global sales of the Initial Product and any additional products. The Company will manufacture and supply the Initial Product to Actavis in bulk form at an agreed upon unit price.

The Actavis Agreement will expire with respect to the Initial Product and any additional products developed in the future ten years after Actavis' first sale of the applicable product, unless terminated earlier, and will automatically renew for additional two year periods thereafter unless either party provides notice of non-renewal. Either party may terminate the Actavis Agreement in the event of an uncured material breach or bankruptcy filing by the other party. Actavis may also terminate the Actavis Agreement for convenience in specified circumstances upon 90 days' prior written notice.

The Company applied revenue recognition guidance to determine whether the performance obligations under this collaboration, including the license, participation on steering committees, development services, and manufacturing and supply services could be accounted for separately or as a single unit of accounting. The Company determined that these obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, the Company has deferred total billed and billable milestones and development expenses of \$3.8 million as of September 30, 2014 and \$2.1 million as of December 31, 2013 related to the Actavis Agreement.

5. Fair Value of Financial Instruments

The carrying value of financial instruments, including cash and cash equivalents, restricted cash, available-for-sale securities, prepaid expenses, accounts receivable, accounts payable and accrued expenses, and other short-term assets and liabilities approximate their respective fair values due to the short-term maturities of these assets and liabilities.

Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value is determined based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect certain market assumptions. As a basis for considering such assumptions, GAAP establishes a three-tier value hierarchy, which prioritizes the inputs used to develop the assumptions and for measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets for identical assets; (Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and (Level 3) unobservable inputs in which there is little or no market data, which requires the Company to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Recurring Fair Value Measurements

The following tables show assets and liabilities measured at fair value on a recurring basis as of September 30, 2014 and December 31, 2013 and the input categories associated with those assets and liabilities:

(in thousands) As of September 30, 2014	Level 1	Level 2	Level 3
Assets:			
Cash equivalents – money market funds	\$90,334	\$ —	\$ —
Cash equivalents – commercial paper	_	3,200	_
Investments – commercial paper	_	3,000	_
Investments – corporate debt securities	_	50,356	_
As of December 31, 2013	Level 1	Level 2	Level 3
Assets:			
Cash equivalents – money market funds	\$47,740	\$ —	\$ —
Cash equivalents – corporate debt securities	_	13,998	_
Investments – commercial paper	_	49,680	_
Investments – corporate debt securities	_	40,436	_

The Company's investment portfolio consists of investments classified as cash equivalents and available-for-sale securities. All highly liquid investments with an original maturity of three months or less when purchased are considered to be cash equivalents. The Company's cash and cash equivalents are invested in U.S. treasury and various corporate debt securities that approximate their face value. All marketable securities with an original maturity when purchased of greater than three months are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss). The amortized cost of securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity.

Other Fair Value Measurements

The estimated fair value of the \$125.0 million aggregate principal amount of the Notes was \$193.1 million as of September 30, 2014. The Company estimated the fair value of the Notes by using a quoted market rate in an inactive market, which is classified as a Level 2 input. The carrying value of the Notes is \$78.6 million due to the bifurcation of the conversion feature of the Notes as described more fully in Note 7, "Borrowings."

The estimated fair value and carrying value of the loans payable under the Loan Agreement with Hercules was \$40.6 million and \$40.5 million, respectively, as of September 30, 2014. The Company estimated the fair value of the loans payable by using publically available information related to Hercules' portfolio of debt investments based on unobservable inputs, which is classified as a Level 3 input.

The immaterial fair value of a derivative liability as of September 30, 2014 was determined using a probability-weighted valuation based upon the likelihood of Silver Creek achieving a qualified financing, which is classified as a Level 3 input, as described in Note 7, "Borrowings."

6. Accounts Payable, Accrued Expenses and Other

Accounts payable, accrued expenses and other as of September 30, 2014 and December 31, 2013 consisted of the following:

(in thousands)	September 30, 2014	December 31, 2013
Accounts payable	\$ 2,639	\$ 1,889
Accrued goods and services	23,910	26,031
Accrued payroll and related benefits	7,359	7,255
Accrued interest	1,551	2,926
Accrued dividends payable	18	25
Deferred tax incentives	512	688
Total accounts payable, accrued expenses and other	\$ 35,989	\$ 38,814

7. Borrowings

Future minimum payments under indebtedness agreements outstanding as of September 30, 2014 are as follows:

(in thousands) As of September 30, 2014:	Convertible nior Notes	Loan Agreement	
Remainder of 2014	\$ _	\$ 4,548	
2015	5,625	18,135	
2016	5,625	23,804	
2017	5,625	_	
2018 and thereafter	141,875	_	
	158,750	46,487	
Less interest	(33,750)	(5,287)	
Less unamortized discount	(46,409)	(1,748)	
Less current portion		(14,615)	
Loans payable, net of current portion	\$ 78,591	\$ 24,837	

4.50% Convertible Senior Notes

In July 2013, the Company issued \$125.0 million aggregate principal amount of Notes in an underwritten public offering. \underline{A} s a result of the Notes offering, the Company received net proceeds of approximately \$120.6 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

The Notes bear interest at a rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2014. The Notes are general unsecured senior obligations of the Company.

The Notes will mature on July 15, 2020 (the "Maturity Date"), unless earlier repurchased by the Company or converted at the option of holders. Holders may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding April 15, 2020 only under certain circumstances. Upon any conversion of Notes that occurs while the Company's indebtedness to Hercules under the Loan Agreement remains outstanding, the Notes will be settled in shares of the Company's common stock. Following the repayment and satisfaction in full of the Company's obligations to Hercules under the Loan Agreement, upon any conversion of the Notes, the Notes may be settled, at the Company's election, in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock.

The initial conversion rate of the Notes is 160 shares of the Company's common stock per \$1,000 principal amount of Notes, which is equivalent to an initial conversion price of \$6.25 per share of common stock. The conversion rate will be subject to adjustment in some events. In addition, following certain corporate events that occur prior to the Maturity Date, the Company will increase the conversion rate for a holder who elects to convert its Notes in connection with such a corporate event in certain circumstances.

The Company has separately accounted for the liability and equity components of the Notes by bifurcating gross proceeds between the indebtedness, or liability component, and the embedded conversion option, or equity component. This bifurcation was done by estimating an effective interest rate as of the date of issuance for similar notes which do not contain an embedded conversion option. The embedded conversion option was recorded in stockholders' deficit and as debt discount, to be subsequently amortized as interest expense over the term of the Notes. Underwriting discounts and commissions and offering expenses totaled \$4.4 million and were allocated to the indebtedness and the embedded conversion option based on their relative values.

For the three and nine months ended September 30, 2014, interest expense related to the outstanding principal balance of the Notes was \$3.4 million and \$10.3 million, respectively. For both the three and nine months ended September 30, 2013, interest expense related to the outstanding principal balance of the Notes was \$2.8 million.

Loan Agreement

In November 2012, the Company entered into the Loan Agreement with Hercules pursuant to which the Company received loans in the aggregate principal amount of \$40.0 million in 2012. The Company, as permitted under the Loan Agreement, had previously extended the interest-only payment period with the aggregate principal balance of the loans to be repaid in monthly installments starting on June 1, 2014 and continuing through November 1, 2016. On June 25, 2014, the Company entered into an amendment to the Loan Agreement, whereby the Company and Hercules agreed to extend until October 1, 2014 the period during which the Company makes interest-only payments. On November 6, 2014, the Company entered into a further amendment to the Loan Agreement, whereby the Company and Hercules agreed to extend by four additional months the period during which the Company makes interest-only payments. As a result, the Company will repay the aggregate outstanding principal balance of the loan in equal monthly installments of principal and interest (based on a 30 month amortization schedule) beginning on February 1, 2015. The remaining principal balance and interest will be due and payable on November 1, 2016. This amendment was treated as a debt modification for accounting purposes.

Upon full repayment or maturity of the loans, the Company is required to pay Hercules a fee of \$1.2 million, which has been recorded as a discount to the loans and as a long-term liability on the Company's condensed consolidated balance sheets. Additionally, the Company reimbursed Hercules for costs incurred related to the loans, which has been reflected as a discount to the carrying value of the loans. The Company is amortizing these loan discounts totaling \$1.6 million to interest expense over the term of the loans using the effective interest method. For the three and nine months ended September 30, 2014, interest expense related to Hercules loans payable was \$1.2 million and \$3.6 million, respectively. For the three and nine months ended September 30, 2013, interest expense related to Hercules loans payable was also \$1.2 million and \$3.7 million, respectively.

In connection with the Loan Agreement, the Company granted Hercules a security interest in all of the Company's personal property now owned or hereafter acquired, excluding intellectual property but including the proceeds from the sale, if any, of intellectual property, and a negative pledge on intellectual property. The Loan Agreement also contains certain representations, warranties and non-financial covenants of the Company.

Convertible Notes - Silver Creek

Between April and September 2014, the Company's majority owned subsidiary, Silver Creek, issued an aggregate of \$0.7 million in convertible notes to multiple legal entities pursuant to a Note Purchase Agreement. The notes bear interest at 6% and mature and convert, along with accrued interest, into Silver Creek Series A preferred stock on December 31, 2014. If at any time prior to maturity Silver Creek enters into a qualifying equity financing, defined as a sale or series of related sales of equity securities prior to the maturity date and resulting in at least \$4.0 million of gross proceeds, the notes will automatically convert into the next qualifying equity financing at a 25% discount. The Company determined that this convertible feature met the definition of a derivative and required separate accounting treatment. The derivative was deemed to be immaterial upon issuance and as of September 30, 2014 using a probability-weighted model, and was recorded as a derivative liability within other current liabilities on the consolidated balance sheets. As of September 30, 2014, Silver Creek had outstanding borrowings of \$0.6 million, net of immaterial debt discounts. For the three and nine months ended September 30, 2014, interest expense related to the outstanding principal balance under the Note Purchase Agreement was immaterial.

8. Common Stock

As of September 30, 2014 and December 31, 2013, the Company had 200.0 million shares of \$0.01 par value common stock authorized. There were approximately 105.7 million and 102.5 million shares of common stock issued and outstanding as of September 30, 2014 and December 31, 2013, respectively.

In February 2014, Hercules exercised warrants to purchase 302,143 shares of common stock for proceeds to the Company of \$1.1 million.

The shares reserved for future issuance as of September 30, 2014 and December 31, 2013 consisted of the following:

(in thousands)	September 30, 2014	December 31, 2013
Options to purchase common stock	20,547	20,107
Common stock warrants	2,402	2,777
Conversion premium on the Notes	25,000	25,000

9. Stock-Based Compensation

As of December 31, 2013, there were 1.7 million shares of common stock available to be granted under the Company's 2011 Stock Incentive Plan (the "2011 Plan"). The 2011 Plan is administered by the Company's board of directors and permits the Company to grant incentive and non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards.

In January 2014, 3.6 million additional shares of common stock became available for grant to employees, officers, directors and consultants under the 2011 Plan. During the nine months ended September 30, 2014 and 2013, the Company issued options to purchase 3.7 million and 3.2 million shares of common stock, respectively. At September 30, 2014, there were 2.0 million shares remaining available for grant under the 2011 Plan.

The assumptions used to estimate the fair value of options granted to employees and directors at the date of grant for the three and nine months ended September 30, 2014 were as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Risk-free interest rate	1.8-2.0%	1.9%	1.6-2.0%	0.1-1.9%
Expected dividend yield	0%	0%	0%	0%
Expected term	5.8-5.9 years	5.9 years	5.0-5.9 years	5.3-5.9 years
Expected volatility	67-72%	67-68%	64-72%	67-68%

Options granted to directors during the three and nine months ended September 30, 2014 vested immediately. Options granted to directors during the three and nine months ended September 30, 2013 vested over a one year period. Options granted to employees generally vest over a three year period. The Company recognized stock-based compensation expense as follows for the three and nine months ended September 30, 2014 and 2013:

	Three months ended September 30,		Nine months end September 30,	
(in thousands)	2014	2013	2014	2013
Employee awards:				
Research and development	\$ 1,663	\$ 1,517	\$5,185	\$4,453
General and administrative	1,143	1,212	4,596	3,609
Stock-based compensation for employee awards	2,806	2,729	9,781	8,062
Stock-based compensation for non-employee awards	44	(192)	160	(109)
Total stock-based compensation	\$2,850	\$ 2,537	\$9,941	\$7,953

The stock-based compensation for non-employee awards recognized during the three and nine months ended September 30, 2013 was negative due to the change in fair value of options granted during previous periods.

The following table summarizes stock option activity during the nine months ended September 30, 2014:

(in thousands, except per share amounts and years)	Number of Shares	Av	eighted verage cise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, December 31, 2013	20,107	\$	3.93	6.11	\$ 38,348
Granted	3,704	\$	5.45		
Exercised	(2,793)	\$	2.27		
Forfeited	(471)	\$	6.30		
Outstanding, September 30, 2014	20,547	\$	4.37	6.38	\$ 90,628
Vested and expected to vest, September 30, 2014	20,220	\$	4.35	6.33	\$ 89,628
Exercisable, September 30, 2014	15,313	\$	3.84	5.50	\$ 75,699

The aggregate intrinsic value was calculated as the difference between the exercise price of the stock options and the fair value of the underlying common stock.

10. Commitments and Contingencies

Operating Leases

The Company leases its office, laboratory and manufacturing space under non-cancelable operating leases. Total rent expense under these operating leases was \$1.4 million and \$1.3 million for the three months ended September 30, 2014 and 2013, respectively. Total rent expense under these operating leases was \$4.4 million and \$4.0 million for the nine months ended September 30, 2014 and 2013, respectively.

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 financial statements and the notes to those financial statements appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2013 included in our Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q, which are incorporated herein by reference, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines consisting of novel therapeutics paired with companion diagnostics for the treatment of cancer. Our mission is to provide patients, physicians and the healthcare system with the medicines, tools and information to transform the approach to care from one based on the identification and treatment of symptoms to one focused on the diagnosis and treatment of illness through a more precise mechanistic understanding of disease. We seek to accomplish our mission by applying our proprietary systems-based approach to biomedical research, which we call Network Biology. Our initial focus is in the field of oncology. We have six novel therapeutics in clinical development. In our most advanced program, we are developing MM-398 as a treatment for metastatic pancreatic cancer.

In May and June 2014, we announced results from our Phase 3 clinical trial of MM-398 in patients with metastatic pancreatic cancer whose cancer has progressed on treatment with gemcitabine. The primary endpoint of this trial was a statistically significant difference in overall survival between MM-398, alone or in combination with 5-fluorouracil, or 5-FU, and leucovorin, against a common control arm of the combination of 5-FU and leucovorin. The combination of MM-398 with 5-FU and leucovorin achieved the primary endpoint for this trial, with a statistically significant survival advantage compared to the control arm. MM-398 monotherapy did not achieve a statistically significant survival advantage compared to the control arm. The combination of MM-398 with 5-FU and leucovorin achieved an overall survival of 6.1 months, a 1.9 month improvement over the 4.2 month survival demonstrated by the control arm of 5-FU and leucovorin alone. The primary log-rank analysis of overall survival for the MM-398 combination arm was statistically significant (p=0.012) with a corresponding hazard ratio of 0.67. A statistically significant advantage in progression free survival was also observed in the combination arm, with a median of 3.1 months compared to 1.5 months in the control arm. The combination arm also showed a statistically significant difference in overall response compared to the control arm (16% and 1%, respectively, p<0.001). The most common non-hematologic Grade 3 and higher adverse events in the MM-398 combination arm were fatigue (14%), diarrhea (13%) and vomiting (11.1%). Hematologic Grade 3 and higher adverse events included neutropenia, which was observed in 2% of patients. The MM-398 monotherapy arm had a 4.9 month median overall survival, compared to 4.2 months in the control arm. For the monotherapy arm, the hazard ratio for overall survival was 0.99 with a corresponding p-value of 0.942. In general, patients experienced a higher level of adverse events with the MM-398 monotherapy dose and treatment schedule

We have devoted substantially all of our resources to our drug discovery and development efforts, including advancing our Network Biology approach, conducting clinical trials for our product candidates, protecting our intellectual property, and providing general and administrative support for these operations. We have not generated any revenue from product sales and, to date, have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings

of our securities and a secured debt financing. Through September 30, 2014, we have received \$268.2 million from the sale of convertible preferred stock and warrants, \$126.7 million of net proceeds from the sale of common stock in our April 2012 initial public offering and July 2013 follow-on underwritten public offering, \$39.6 million of net proceeds from a secured debt financing, \$120.6 million of net proceeds from the issuance of 4.50% convertible senior notes due 2020, or the convertible senior notes, in our July 2013 underwritten public offering, \$100.0 million of upfront fees from our license and collaboration agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, collectively Baxter, and \$239.9 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our other development collaborations. We have also entered into an arrangement to use our manufacturing capabilities to manufacture drug product on behalf of Watson Laboratories, Inc., or Actavis, for which we have received \$2.9 million in upfront fees and reimbursements as of September 30, 2014. As of September 30, 2014, we had unrestricted cash and cash equivalents and available-for-sale securities of \$153.7 million. We expect that our existing unrestricted cash and cash equivalents and available-for-sale securities as of September 30, 2014 and anticipated cost sharing reimbursements under our license and collaboration agreement with Baxter related to MM-398 will enable us to fund operations into the second half of 2015.

We have never been profitable and, as of September 30, 2014, we had an accumulated deficit of \$645.8 million. Our net loss was \$28.0 million and \$74.1 million for the three and nine months ended September 30, 2014, respectively, and \$39.8 million and \$98.3 million for the three and nine months ended September 30, 2013, respectively. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical trials of our product candidates, including multiple simultaneous clinical trials for certain product candidates, some of which we expect will be entering late stage clinical development.

In addition, in connection with seeking and possibly obtaining regulatory approval of any of our product candidates, including MM-398 for which we plan to submit a new drug application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for the combination of MM-398 with 5-FU and leucovorin, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. We will need to generate significant revenues to achieve profitability, and we may never do so.

Strategic Partnerships, Licenses and Collaborations

Baxter

On September 23, 2014, we entered into a license and collaboration agreement with Baxter, which we refer to as the Baxter agreement, for the development and commercialization of MM-398 outside of the United States and Taiwan, or the licensed territory. As part of the Baxter agreement, we granted Baxter an exclusive, royalty-bearing right and license under our patent rights and know-how to develop and commercialize MM-398 in the licensed territory. Baxter is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercialize MM-398 in the licensed territory. A joint steering committee comprised of an equal number of representatives from each of Baxter and us is responsible for approving changes to the global development plan for MM-398, including all budgets, and overseeing the parties' development and commercialization activities with respect to MM-398. Unless otherwise agreed, we will be responsible for conducting all clinical trials contemplated by the global development plan for MM-398.

Under the terms of the Baxter agreement, we received a \$100.0 million upfront, nonrefundable cash payment. In addition, we are eligible to receive from Baxter (i) up to an aggregate of \$100.0 million upon the achievement of specified research and development milestones, (ii) up to an aggregate of \$520.0 million upon the achievement of specified regulatory milestones and (iii) up to an aggregate of \$250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxter agreement, we will bear up to the first \$98.8 million of costs related to the development of MM-398 for pancreatic cancer patients who have not previously received gemcitabine; however, we expect most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. We will share equally with Baxter all other clinical trial costs contemplated by the global development plan. We are also entitled to tiered, escalating royalties ranging from sub-teen double-digits to low twenties percentages of net sales of MM-398 in the licensed territory.

We expect to enter into a commercial supply agreement with Baxter pursuant to which we will supply MM-398 bulk drug substance to Baxter and, at Baxter's option, may manage fill and finish activities to be conducted by a third party contract manufacturer for Baxter. Baxter also has the option to manufacture MM-398 itself, in which case we will perform a technology transfer of our manufacturing process to Baxter.

If not terminated earlier by either party, the Baxter agreement will expire upon expiration of all royalty and other payment obligations of Baxter under the Baxter agreement. Either party may terminate the Baxter agreement in the event of an uncured material breach by the other party. Baxter may also terminate the Baxter agreement on a product-by-product, country-by-country or sub-territory-by-sub-territory basis or in its entirety, for its convenience, upon 180 days' prior written notice. In addition, we may terminate the Baxter agreement if Baxter challenges or supports any challenge of our licensed patent rights.

Under the Baxter agreement, we granted Baxter a right of first negotiation to obtain a license to develop and commercialize MM-111, MM-141 and MM-302 outside of the United States. Baxter has also agreed that, subject to limited exceptions, until September 23, 2017, neither Baxter nor any of its affiliates will (1) effect or seek, offer or propose to effect, or cause or participate in or in any way advise, assist or encourage any other person to effect or seek, offer or propose to effect or cause or participate in, any acquisition of any of our securities or assets, any tender or exchange offer, merger or other business combination involving us, any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to us, or any solicitation of proxies or consents to vote any of our voting securities; (2) form, join or in any way participate in a group with respect to any of our securities; (3) otherwise act, alone or in concert with others, to seek to control or influence our management, board of directors or policies; (4) take any action that might force us to make a public announcement regarding any of the foregoing; or (5) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing.

At the inception of the collaboration, we identified the following deliverables as part of the Baxter agreement: (i) license to develop and commercialize MM-398 in Baxter's territories, (ii) discovery, research, development and manufacturing services required to complete ongoing clinical trials related to MM-398, (iii) discovery, research, development and manufacturing services needed to complete future clinical trials in further indications related to MM-398, (iv) the option to perform a technology transfer of our manufacturing process related to the production of MM-398 to Baxter and (v) participation on the joint steering committee.

We concluded that none of the deliverables identified at the inception of the collaboration has standalone value from the other undelivered elements. As such, all deliverables represent a single unit of accounting.

We have determined that the collaboration represents a services agreement and as such have estimated the level of effort expected to be incurred as a result of providing the identified deliverables. We will recognize revenue from the upfront payment, non-substantive milestone payments and payments related to discovery, research, development and technology transfer services based on proportional performance as effort is incurred over the expected services period.

Research, development and regulatory milestones that are considered substantive on the basis of the contingent nature of the milestone will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All sales milestones will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

During the three and nine months ended September 30, 2014, we recognized no revenue associated with the Baxter agreement. As of September 30, 2014, there was \$100 million of deferred revenue related to the Baxter agreement, \$47.5 million of which is classified as current, with the remainder classified as non-current in the condensed consolidated balance sheets based upon our estimate of revenue that will be recognized within the next twelve months.

Sanofi

In September 2009, we entered into a license and collaboration agreement with Sanofi, which we refer to as the Sanofi agreement, for the development and commercialization of MM-121. Through September 30, 2014, Sanofi has paid us a nonrefundable, noncreditable upfront license fee of \$60.0 million, as well as additional aggregate milestone payments of \$25.0 million. Under the Sanofi agreement, Sanofi is also responsible for all MM-121 development and manufacturing costs. Sanofi reimburses us for internal time at a designated full-time equivalent rate per year and reimburses us for direct costs and services related to the development and manufacturing of MM-121.

On June 17, 2014, we agreed with Sanofi to terminate the Sanofi agreement effective December 17, 2014, although we have the right to accelerate such termination date. In connection with the agreement to terminate the Sanofi agreement, among other things, Sanofi transferred ownership of the investigational new drug application for MM-121 back to us in July 2014, and we have waived Sanofi's obligation to reimburse us for MM-121 development costs incurred after the effective termination date.

The timing of cash received from Sanofi differs from revenue recognized for financial statement purposes. We recognize revenue for development services within the period they are incurred and billable. Billable expenses are defined during each specified budget period. For the three and nine months ended September 30, 2014, the specified budget period comprises the period ending December 17, 2014. In the event that total development services expense incurred and expected to be incurred during any particular budget period exceed the total contractually allowed billable amount for development services during the same period, we recognize only a percentage of the development services incurred as revenue in that period.

This percentage is calculated as total development services expense incurred during the specified period divided by the sum of total development services expense incurred plus estimated development services expense to be incurred during the specified period, multiplied by the total contractually allowed billable amount for development services during the specified period, less development services revenue recognized within the specified period. We recognize revenue on expenses incurred in excess of this percentage in the budget period when the excess amounts become contractually billable. We also recognize revenue for the upfront payment, milestone payments and manufacturing services using the contingency-adjusted performance model over the expected development period, which was initially estimated to be 12 years from the effective date of the Sanofi agreement. As a result of the agreement to terminate the Sanofi agreement, the development period was revised to end as of December 17, 2014. During the three and nine months ended September 30, 2014 and 2013, we recognized revenue based on the following components of the Sanofi agreement:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2014	2013	2014	2013
Upfront payment	\$13,415	\$1,250	\$27,933	\$ 3,750
Milestone payments	5,590	521	11,639	1,562
Development services	2,953	4,521	16,694	30,794
Manufacturing services and other	6,044	564	12,585	3,304
Total	\$28,002	\$6,856	\$68,851	\$39,410

The increase in the revenue recognition over the three and nine months ended September 30, 2014 is due to the reduced development period under the Sanofi agreement, which will terminate effective December 17, 2014 unless we choose to accelerate the termination date.

Actavis

In November 2013, we entered into a development, license and supply agreement with Actavis, which we refer to as the Actavis agreement, pursuant to which we will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection, or the initial product, to Actavis. Under the Actavis agreement, Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the Actavis agreement, we have also agreed to develop additional products for Actavis in the future, the identities of which will be mutually agreed upon. We are eligible to receive up to \$15.5 million, of which \$2.9 million has been received through September 30, 2014, and the remainder in development funding and development, regulatory and commercial milestone payments related to the initial product. We will also receive a double digit percentage of net profits on global sales of the initial product and any additional products. We will manufacture and supply the initial product to Actavis in bulk form at an agreed upon unit price.

The Actavis agreement will expire with respect to the initial product and any additional products developed in the future ten years after Actavis' first sale of the applicable product, unless terminated earlier, and will automatically renew for additional two year periods thereafter unless either party provides notice of non-renewal. Either party may terminate the Actavis agreement in the event of an uncured material breach or bankruptcy filing by the other party. Actavis may also terminate the agreement for convenience in specified circumstances upon 90 days' prior written notice.

We applied revenue recognition guidance to determine whether the performance obligations under this collaboration, including the license, participation on steering committees, development services, and manufacturing and supply services, could be accounted for separately or as a single unit of accounting. We determined that these obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, we have deferred total billed and billable milestones and development expenses of \$3.8 million and \$2.1 million as of September 30, 2014 and December 31, 2013, respectively, related to the Actavis agreement.

Financial Obligations Related to the License and Development of MM-398

In September 2005, Hermes BioSciences, Inc., or Hermes, which we acquired in October 2009, entered into a license agreement with PharmaEngine, Inc., or PharmaEngine, under which PharmaEngine received an exclusive license to research, develop, manufacture and commercialize MM-398 in Europe and certain countries in Asia. In May 2011, we entered into a new agreement with PharmaEngine, which we refer to as the PharmaEngine agreement, under which we reacquired all previously licensed rights for MM-398, other than rights to commercialize MM-398 in Taiwan.

On September 22, 2014, we amended the PharmaEngine agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that we are required to pay to PharmaEngine. As a result of this amendment, we made a \$7.0 million milestone payment to PharmaEngine. Additionally, as a result of this amendment, a previously contingent \$5.0 million milestone payment is now payable to PharmaEngine upon the earlier of either the FDA's acceptance of an NDA for MM-398 or April 30, 2015. Prior to the amendment of the PharmaEngine agreement, this milestone payment was contingent upon the award of certain specified regulatory designations. These milestone payments were recognized as research and development expense during the three months ended September 30, 2014.

Since entering into the PharmaEngine agreement, we have paid PharmaEngine an aggregate of \$22.0 million in upfront license fees and milestone payments. In addition to the \$5.0 million milestone payment, we will also be required to pay PharmaEngine up to an additional \$70.0 million in aggregate regulatory milestones and \$130.0 million in aggregate sales milestones, in each case with respect to Europe and certain countries in Asia. PharmaEngine is also entitled to tiered royalties on net sales of MM-398 in Europe and certain countries in Asia. The royalty rates under the PharmaEngine agreement range from high single digits up to the low teens as a percentage of our net sales of MM-398 in these territories. Under the PharmaEngine agreement, we are responsible for all future development costs of MM-398 except those required specifically for regulatory approval in Taiwan. During the three months ended September 30, 2014 and 2013, we recognized research and development expenses of \$12.4 million and \$0.5 million, respectively. During the nine months ended September 30, 2014 and 2013, we recognized research and development expenses of \$12.5 million and \$1.0 million, respectively, related to the PharmaEngine agreement.

Our financial obligations under other license and development agreement are summarized below under "—Liquidity and Capital Resources—Contractual obligations and commitments."

Financial Operations Overview

Revenues

We have not yet generated any revenue from product sales. All of our revenue to date has been derived from license fees, milestone payments and research, development, manufacturing and other payments received from collaborations, and, to a lesser extent, from grant payments received from the National Cancer Institute. In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and research, development and manufacturing payments from collaborations and royalties from the sales of products developed under licenses of our intellectual property.

We expect that any revenue we generate over the next 12 months will fluctuate quarter to quarter as a result of the timing and amount of license fees, research, development and manufacturing reimbursements, milestone and other payments from collaborations. Additionally, to the extent that any of our products are successfully commercialized, we expect that any revenue generated in the future will also fluctuate quarter to quarter as a result of the amount and timing of payments that we receive upon the sale of our products. We do not expect to generate revenue from product sales until 2015 at the earliest. If we or our collaborators fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

We expect to begin to recognize revenue related to the Baxter agreement in the fourth quarter of 2014. In addition, we expect that revenues in 2015 under the Baxter agreement will exceed revenues in 2014 as we will have performed a full year of services under the Baxter agreement.

We expect development revenues under our Sanofi agreement to be lower in 2014 as compared to 2013 due to lower expected MM-121 expenses as existing trials wind down. In addition, we have agreed with Sanofi that the Sanofi agreement will terminate effective December 17, 2014 unless we choose to accelerate such termination date, and we therefore expect non-development revenues under the Sanofi agreement to be higher in 2014 compared to 2013. We do not expect to receive any revenues under the Sanofi agreement after December 17, 2014.

Research and development expense

The following table summarizes our principal product development programs, including the latest related stages of development for each product candidate in development and the research and development expenses allocated to each clinical product candidate.

		Current stage of	Three mor Septem	nths ended lber 30,	Nine mon Septem	
(in thousands)	Indication	development	2014	2013	2014	2013
MM-398	Cancer	Phase 3	\$16,361	\$ 7,541	\$ 26,275	\$ 23,058
MM-121	Cancer	Phase 2	2,949	11,522	7,598	38,342
MM-111	Cancer	Phase 2	3,094	3,481	11,564	12,220
MM-302		Phase 2				
	Cancer	initiated	3,103	2,699	10,804	6,193
MM-151	Cancer	Phase 1	1,405	1,557	7,812	4,833
MM-141	Cancer	Phase 1	4,138	1,434	9,716	5,577
Preclinical, general research and discovery			10,914	7,879	28,787	22,408
Stock compensation			1,668	1,517	5,195	4,453
Total research and development expense			\$43,632	\$37,630	\$107,751	\$117,084

The development, regulatory and clinical expenses related to the Actavis agreement are included within our preclinical, general research and discovery expenses. MM-398 research and development expense includes \$12 million of milestone payments owed to PharmaEngine as a result of our September 2014 amendment to the PharmaEngine agreement.

MM-398

In May and June 2014, we announced results from our Phase 3 clinical trial of MM-398 in patients with metastatic pancreatic cancer whose cancer has progressed on treatment with gemcitabine. In this trial, the combination of MM-398 with 5-FU and leucovorin achieved a statistically significant survival advantage compared to the control arm of 5-FU and leucovorin. We are continuing to evaluate the complete results of this trial. Our current estimate of the remaining external costs associated with completing the Phase 3 clinical trial is between \$5.0 million and \$6.0 million, reflecting an increase which is related to updated estimates of patient treatment and survival across the trial arms. We plan to submit an NDA to the FDA for the combination of MM-398 with 5-FU and leucovorin. We are also conducting a Phase 1 translational study to identify predictive biomarkers associated with MM-398. A translational study is a clinical trial where biomarker investigation is performed, with a goal of identifying biomarkers that predict patients' response to the therapy. In addition, several trials are ongoing in which the majority of the total clinical trial costs are paid for by the investigators. These trials include an investigator-sponsored Phase 2 clinical trial in colorectal cancer, an investigator-sponsored Phase 1 clinical trial in glioma and an investigator-initiated Phase 1 clinical trial in pediatric solid tumors.

In the first quarter of 2012, we made a milestone payment of \$5.0 million to PharmaEngine in connection with dosing the first patient in our Phase 3 clinical trial. In the third quarter of 2014, we made a milestone payment of \$7.0 million to PharmaEngine in connection with entering into the Baxter agreement. We are obligated to pay PharmaEngine an additional \$5.0 million milestone payment upon the earlier of either the FDA's acceptance of an NDA for MM-398 or April 30, 2015. We are not obligated to make any other milestone payments to PharmaEngine with respect to regulatory submissions or approvals in the United States. We will also be required to pay PharmaEngine up to an additional \$70.0 million in aggregate regulatory milestones and \$130.0 million in aggregate sales milestones, in each case with respect to Europe and certain countries in Asia. PharmaEngine is also entitled to tiered royalties based on net sales of MM-398 in Europe and certain countries in Asia. The royalty rates range from high single digits up to the low teens as a percentage of net sales of MM-398 in these territories.

MM-121

In September 2009, we entered into the Sanofi agreement related to MM-121. On June 17, 2014, we agreed with Sanofi that the Sanofi agreement will terminate effective December 17, 2014 unless we choose to accelerate such termination date. Under the terms of the agreement, we are currently responsible for executing clinical trials through the development period ending on the effective termination date. We separately record revenue and expenses on a gross basis under this arrangement. Sanofi remains responsible for all development and manufacturing costs of MM-121 through the effective termination date. We are currently concluding four Phase 2 clinical trials and three Phase 1 clinical trials of MM-121 in multiple cancer types.

We expect MM-121 expenses to be lower in 2014 compared to 2013 as the Phase 2 clinical trials that we are conducting are brought to their conclusions and until such time as we finalize the future development plan for MM-121, including any clinical trials to be initiated. Upon completion of the 2014 development plan, we expect MM-121 expenses to again increase as we execute upon 2014 and future development plans, and as a result of Sanofi ceasing to be responsible for development and manufacturing costs of MM-121.

MM-111

We are currently conducting a Phase 2 clinical trial of MM-111 in gastric, esophageal and gastroesophageal cancers and a Phase 1 clinical trial of MM-111 in solid tumors.

MM-302

We are currently conducting one Phase 1 clinical trial and have initiated a Phase 2 clinical trial of MM-302 in breast cancer.

MM-151

We are currently conducting one Phase 1 clinical trial of MM-151 in solid tumors.

MM-141

We are currently conducting one Phase 1 clinical trial of MM-141 in solid tumors.

General and administrative expense

General and administrative expense consists primarily of salaries and other related costs for personnel, including stock-based compensation expenses and benefits, in our legal, intellectual property, business development, finance, purchasing, accounting, information technology, corporate communications, investor relations and human resources departments. Other general and administrative

expenses include employee training and development, board of directors costs, depreciation, insurance expenses, facility-related costs not otherwise included in research and development expense, professional fees for legal services, including patent-related expenses, pre-commercialization costs, and accounting and information technology services. We expect that general and administrative expense will increase in future periods in proportion to increases in research and development and as a result of increased payroll, expanded infrastructure, increased consulting, legal, accounting and investor relations expenses associated with being a public company and costs incurred to develop and commercialize our clinical products. In addition, we expect that general and administrative expense will increase significantly upon the initiation of commercialization activities as a result of the favorable results obtained for the combination of MM-398 with 5-FU and leucovorin from our Phase 3 clinical trial.

Interest expense

Interest expense consists primarily of cash and non-cash interest recorded on our loans payable and convertible senior notes. We expect that interest expense will continue to be higher in 2014 as compared to 2013, continuing through the time periods that our loans payable and convertible senior notes remain outstanding.

Other income

Other income consists primarily of the recognition of tax incentives and other one-time income or expense-related items.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or the SEC, and generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed 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 financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Estimates include revenue recognition, lease accounting, valuation of embedded conversion options, useful lives with respect to long-lived assets and intangibles, valuation of stock options, contingencies, accrued expenses and other, intangible assets, goodwill, in-process research and development and tax valuation reserves. We base our estimates on 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. Our actual results may differ from these estimates under different assumptions or conditions.

Upon entering the Baxter agreement, we were required to make estimates and assumptions regarding the units of accounting and the inputs used in the revenue recognition model. We will evaluate these estimates and judgments on an ongoing basis going forward.

Our critical accounting policies and the methodologies and assumptions we apply under then have not materially changed since March 4, 2014, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2013. For more information on our critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2013.

Results of Operations

Comparison of the three months ended September 30, 2014 and 2013

	Three months ended September 30,	
(in thousands)	2014	2013
Collaboration revenues	\$ 28,002	\$ 6,856
Research and development expenses	43,632	37,630
General and administrative expenses	8,095	5,150
Loss from operations	(23,725)	(35,924)
Interest income	7	36
Interest expense	(4,585)	(3,946)
Other income	265	71
Net loss	\$(28,038)	\$(39,763)

Collaboration revenues

Collaboration revenues for the three months ended September 30, 2014 were \$28.0 million, compared to \$6.9 million for the three months ended September 30, 2013, an increase of \$21.1 million, or 308%. This increase was primarily attributable to the reassessment of the development period of the Sanofi collaboration based on the decision to terminate the arrangement, which will end effective December 17, 2014 unless we choose to accelerate the termination date, as well as to the winding down and completion of currently existing clinical trials and related recognition of remaining development services budgeted through the year ended December 31, 2014.

Research and development expenses

Research and development expenses for the three months ended September 30, 2014 were \$43.6 million, compared to \$37.6 million for the three months ended September 30, 2013, an increase of \$6.0 million, or 16%. This increase was primarily attributable to:

- \$8.8 million of increased MM-398 expenses primarily due to obligations to make milestone payments to PharmaEngine as a result of the
 amended agreement, offset by decreased costs associated with analyzing and nearing completion of our Phase 3 clinical trial in metastatic
 pancreatic cancer;
- \$3.0 million of increased expenses on preclinical, general research and discovery primarily due to an increased number of preclinical programs in our pipeline and increased costs associated with each preclinical program as these programs approach clinical development; and
- \$2.7 million of increased expenses related to ongoing clinical trials and diagnostic efforts and manufacturing campaigns for our ongoing MM-141 clinical trial.

These increases were partially offset by \$8.5 million of decreased MM-121 expenses primarily due to costs associated with analyzing and concluding ongoing and completed clinical trials.

General and administrative expenses

General and administrative expenses for the three months ended September 30, 2014 were \$8.1 million, compared to \$5.2 million for the three months ended September 30, 2013, an increase of \$2.9 million, or 57%. This increase was primarily attributable to increases in labor and labor-related costs, efforts to prepare for commercialization of our product candidates and increased facility-related costs.

Interest expense

Interest expense for the three months ended September 30, 2014 was \$4.6 million, compared to \$3.9 million for the three months ended September 30, 2013. This increase was primarily attributable to the interest recorded on the convertible senior notes issued in July 2013.

Comparison of the nine months ended September 30, 2014 and 2013

	Nine months ended September 30,	
(in thousands)	2014	2013
Collaboration revenues	\$ 68,851	\$ 39,963
Research and development expenses	107,751	117,084
General and administrative expenses	22,240	15,177
Loss from operations	(61,140)	(92,298)
Interest income	62	123
Interest expense	(13,666)	(6,459)
Other income	662	297
Net loss	\$ (74,082)	\$(98,337)

Collaboration revenues

Collaboration revenues for the nine months ended September 30, 2014 were \$68.9 million, compared to \$40.0 million for the nine months ended September 30, 2013, an increase of \$28.9 million, or 72%. This increase was primarily attributable to the reassessment of the development period of the Sanofi collaboration based on the decision to terminate the arrangement, which will end effective December 17, 2014 unless we choose to accelerate the termination date, as well as to the winding down and completion of currently existing trials and related recognition of remaining development services budgeted through the year ended December 31, 2014.

Research and development expenses

Research and development expenses for the nine months ended September 30, 2014 were \$107.8 million, compared to \$117.1 million for the nine months ended September 30, 2013, a decrease of \$9.3 million, or 8%. This decrease was primarily attributable to \$30.7 million of decreased MM-121 expenses primarily due to costs associated with analyzing and concluding ongoing and completed clinical trials. This decrease was partially offset by:

- \$6.4 million of increased expenses on preclinical, general research and discovery primarily due to an increased number of preclinical programs in our pipeline and increased costs associated with each preclinical program as these programs approach clinical development;
- \$4.6 million of increased MM-302 expenses primarily due to costs associated with our ongoing clinical trials as well as the timing of manufacturing campaigns;
- \$4.1 million of increased MM-141 expenses primarily due to costs associated with a manufacturing campaign as well as ongoing clinical trials and diagnostic efforts;
- \$3.2 million of increased MM-398 expenses primarily due to \$12.0 million of non-recurring milestone payment obligations incurred as a result of the amendment of the PharmaEngine agreement, offset by decreased costs associated with analyzing and nearing completion of our Phase 3 clinical trial in metastatic pancreatic cancer; and
- \$3.0 million of increased MM-151 expenses primarily due to costs associated with a manufacturing campaign as well as ongoing clinical trials and diagnostic efforts.

General and administrative expenses

General and administrative expenses for the nine months ended September 30, 2014 were \$22.2 million, compared to \$15.2 million for the nine months ended September 30, 2013, an increase of \$7.1 million, or 47%. This increase was primarily attributable to increases in labor and labor-related costs, efforts to prepare for the commercialization of our product candidates and increased facility-related costs.

Interest expense

Interest expense for the nine months ended September 30, 2014 was \$13.7 million, compared to \$6.5 million for the nine months ended September 30, 2013. This increase was primarily attributable to the interest recorded on the convertible senior notes issued in July 2013.

Liquidity and Capital Resources

Sources of liquidity

We have financed our operations to date primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities and a secured debt financing. Through September 30, 2014, we have received \$268.2 million from the sale of convertible preferred stock and warrants, \$126.7 million of net proceeds from the sale of common stock in our initial public offering and July 2013 follow-on underwritten public offering, \$39.6 million of net proceeds from a secured debt financing, \$120.6 million of net proceeds from the issuance of the convertible senior notes in our July 2013 underwritten public offering, \$100.0 million of upfront fees from our license and collaboration agreement with Baxter and \$239.9 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaboration with Sanofi, which will terminate effective December 17, 2014 unless we choose to accelerate the termination date. We have also entered into an arrangement to use our manufacturing capabilities to manufacture drug product on behalf of Actavis, for which we have received \$2.9 million in upfront fees and reimbursements as of September 30, 2014. As of September 30, 2014, we had unrestricted cash and cash equivalents and available-for-sale securities of \$153.7 million

As of September 30, 2014, within our unrestricted cash and cash equivalents, \$0.3 million was cash and cash equivalents held by our majority owned subsidiary, Silver Creek Pharmaceuticals, Inc., or Silver Creek, which is consolidated for financial reporting purposes. This \$0.3 million held by Silver Creek is designated for the operations of Silver Creek.

Cash flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2014 and 2013.

		iths ended aber 30,
(in thousands)	2014	2013
Cash used in operating activities	\$ (3,123)	\$ (67,750)
Cash provided by (used in) investing activities	31,085	(13,676)
Cash provided by financing activities	7,275	149,163
Net increase in cash and cash equivalents	\$35,237	\$ 67,737

Operating activities

Cash used in operating activities of \$3.1 million during the nine months ended September 30, 2014 was primarily a result of our net loss of \$74.1 million as well as a decrease in deferred revenue due to the reassessment of the development period with Sanofi. These changes were partially offset by an

increase in deferred revenue attributable to the \$100.0 million upfront payment received from Baxter as well as \$19.1 million of non-cash items. Cash used in operating activities of \$67.8 million during the nine months ended September 30, 2013 was primarily a result of our net loss of \$98.3 million, partially offset by non-cash items of \$13.0 million, which included a \$0.8 million impairment charge to in-process research and development for an early stage preclinical program and changes in operating assets and liabilities of \$17.6 million.

Investing activities

Cash provided by investing activities during the nine months ended September 30, 2014 was primarily due to the maturities of marketable securities of \$106.7 million, which was partially offset by purchases of marketable securities of \$70.9 million, as well as \$4.7 million related to the purchase of property and equipment. Cash used in investing activities during the nine months ended September 30, 2013 was primarily due to purchases of available-for-sale securities net of proceeds from sales and maturities of \$4.6 million, as well as \$9.1 million of property and equipment purchases.

Financing activities

Cash provided by financing activities during the nine months ended September 30, 2014 was primarily a result of \$6.5 million of proceeds from the issuance of common stock related to stock option and common stock warrant exercises as well as \$0.7 million of proceeds from the sale and issuance of convertible notes by Silver Creek. Cash provided by financing activities for the nine months ended September 30, 2013 was primarily a result of \$26.7 million of proceeds from an equity financing, net of offering costs in July 2013, \$120.6 million proceeds from the convertible senior notes offering in July 2013, net of offering costs, and \$1.6 million of proceeds from the exercise of common stock options.

Borrowings and other liabilities

We have convertible debt outstanding as of September 30, 2014 related to our 4.50% convertible senior notes due 2020, which we issued in July 2013 in the aggregate principal amount of \$125.0 million. The convertible senior notes are convertible into common stock upon satisfaction of certain conditions. The convertible senior notes bear interest at a fixed rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year. The convertible senior notes will mature on July 15, 2020 unless earlier repurchased by us or converted at the option of holders. See Note 7, "Borrowings," in the accompanying notes to condensed consolidated financial statements for additional information.

In November 2012, we entered into a \$40.0 million Loan and Security Agreement, or loan agreement, with Hercules Technology Growth Capital, Inc., or Hercules, which, as amended, provides for interest-only payments until October 1, 2014. Beginning on October 1, 2014, the aggregate outstanding principal balance of the loans is due in equal monthly installments of principal and interest (based on a 30 month amortization schedule), with the remaining principal balance and interest due and payable on November 1, 2016. An additional \$1.2 million is due upon final repayment of the loans.

Funding requirements

We have not completed development of any therapeutic products or companion diagnostics. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- initiate or continue clinical trials of our six most advanced product candidates;
- continue the research and development of our other product candidates;
- seek to discover additional product candidates;

- seek regulatory approvals for our product candidates that successfully complete clinical trials, including MM-398 in combination with 5-FU and leucovorin;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize products for which we may seek regulatory approval, including MM-398 in combination with 5-FU and leucovorin; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

As of September 30, 2014, we had unrestricted cash and cash equivalents and available-for-sale securities of \$153.7 million. We expect that our existing unrestricted cash and cash equivalents and available-for-sale securities as of September 30, 2014 and anticipated cost sharing reimbursements under our license and collaboration agreement with Baxter related to MM-398 will enable us to fund operations into the second half of 2015. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we utilize collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our six most advanced product candidates;
- the success of our collaborations with Baxter and PharmaEngine related to MM-398 and any future collaborations with other parties that we may enter into;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to establish and maintain commercial manufacturing arrangements for the manufacture of drug product on behalf of third-party pharmaceutical companies; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external sources of funds, other than our collaboration with Baxter for the development and commercialization of MM-398, which is terminable by Baxter for convenience upon 180 days' prior written notice, our collaboration with Sanofi for the development and commercialization of MM-121, which we have agreed with Sanofi will terminate effective December 17, 2014 unless we choose to

accelerate such termination date, and under our development, license and supply agreement with Actavis, which is terminable by Actavis for convenience in specified circumstances upon 90 days' prior written notice. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, if we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

In May 2014, we received an award of \$0.6 million of tax incentives from the Massachusetts Life Sciences Center, which allows us to monetize approximately \$0.6 million of state research and development tax credits. In exchange for these incentives, we pledged to hire an incremental 31 employees and to maintain the additional headcount through at least December 31, 2018. We achieved this pledge in the third quarter of 2014; however, failure to maintain this commitment could result in us being required to repay some or all of these incentives.

In July 2014, we agreed with Sanofi to purchase certain existing drug supply of MM-121. The estimated total cost of this drug supply is approximately \$5.2 million. This drug supply is expected to be released in 2015 and is expected to supply currently projected drug needs into the second half of 2016.

As of September 30, 2014, there were no other material changes to our contractual obligations and commitments outside the ordinary course of business.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board, or FASB, issued guidance to address the diversity in practice related to the financial statement presentation of unrecognized tax benefits as either a reduction of a deferred tax asset or a liability when a net operating loss carryforward, a similar tax loss or a tax credit carryforward exists. This guidance was effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In May 2014, the FASB issued guidance 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. This guidance will be effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is not permitted. We are currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on our consolidated financial statements.

In August 2014, the FASB issued guidance outlining management's responsibility to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date the financial statements are issued and providing guidance on determining when and how to disclose going concern uncertainties in the financial statements. This guidance will be effective for annual and interim reporting periods ending after December 15, 2016, with early adoption permitted. We do not anticipate a material impact to our consolidated financial statements as a result of this change.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We invest in a variety of financial instruments, principally cash deposits, money market funds, securities issued by the U.S. government and its agencies and corporate debt securities. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk.

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 1% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability and intention to hold our investments until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

We do not currently have any auction rate or mortgage-backed securities. We do not believe our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity, however we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value.

The term loans under the loan agreement with Hercules bear interest at variable rates. We have an aggregate principal amount of \$40.0 million outstanding under this facility. Interest is payable at an annual rate equal to the greater of 10.55% and 10.55% plus the prime rate of interest minus 5.25%, but may not exceed 12.55%. As a result of the 12.55% maximum annual interest rate, we have limited exposure to changes in interest rates on borrowings under this facility. For each 1% increase in the interest rate on the outstanding debt amount, subject to a maximum 2% increase, we would have an increase in future cash outflows of approximately \$0.4 million over the next twelve month period.

The convertible senior notes bear interest at a fixed rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year. As a result, we are not subject to interest rate risk with respect to the convertible senior notes.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the

company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2014 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.

We are currently engaged in an opposition proceeding in the European Patent Office to narrow or invalidate the claims of a European patent owned by a third party. In September 2008, we filed a notice of opposition to a patent (EP 1187634) held by Zensun (Shanghai) Science and Technology Ltd., or Zensun, on the grounds of added matter, insufficient disclosure, lack of novelty and lack of inventive step. If the issued claims of the Zensun patent were determined to be valid and construed to cover MM-111, our development and commercialization of MM-111 in Europe could be delayed or prevented. In August 2010, the European Patent Office issued a written decision revoking Zensun's patent. Zensun has appealed this decision. Pending the outcome of this appeal, the original issued claims of the Zensun patent remain in effect. Each party has submitted written statements regarding the appeal to the European Patent Office. Oral proceedings for the appeal are scheduled for March 2015. Although we have obtained a favorable interim decision in this opposition, that decision is now under appeal and the ultimate outcome of this opposition remains uncertain.

We are not currently a party to any other material legal proceedings.

Item 1A. Risk Factors.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was \$74.1 million for the nine months ended September 30, 2014, \$130.7 million for the year ended December 31, 2013 and \$91.8 million for the year ended December 31, 2012. As of September 30, 2014, we had an accumulated deficit of \$645.8 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities and a secured debt financing. We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed development of or commercialized any therapeutic product candidates or companion diagnostics. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- initiate or continue clinical trials of our six most advanced product candidates;
- continue the research and development of our other product candidates;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials, including MM-398 in combination with 5-FU and leucovorin;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize products for which we may seek regulatory approval, including MM-398 in combination with 5-FU and leucovorin; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

To become and remain profitable, we must succeed in developing and eventually commercializing products with significant market potential. This will require us to be successful in a range of challenging activities, including discovering product candidates, completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

Our substantial indebtedness may limit cash flow available to invest in the ongoing needs of our business.

We currently have and will continue to have a significant amount of indebtedness. As of September 30, 2014, we had outstanding borrowings in an aggregate principal amount of \$40.0 million under the loan agreement with Hercules. In addition, on July 17, 2013, we issued \$125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020. We could in the future incur additional indebtedness beyond such amounts.

Our substantial debt combined with our other financial obligations and contractual commitments could have significant adverse consequences, including:

- requiring us to dedicate a substantial portion of cash flow from operations to the payment of interest on, and principal of, our debt, which will
 reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- obligating us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- · limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

In addition, we are vulnerable to increases in the market rate of interest because our currently outstanding secured debt bears interest at a variable rate. If the market rate of interest increases, we will have to pay additional interest on our outstanding debt, which would reduce cash available for our other business needs.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and available-for-sale securities and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt

instruments as a result of an event of default, including upon the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, properties, assets or condition or a failure to pay any amount due, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. In addition, the covenants under our existing debt instruments and the pledge of our assets as collateral limit our ability to obtain additional debt financing.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our obligations.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. We currently do not generate cash flow from operations and, in the future, our business may not generate cash flow from operations sufficient to service our debt and make necessary capital expenditures. If we are unable to generate cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity or debt financing on terms that may be unfavorable to us or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities at all or engage in these activities on desirable terms, which could result in a default on our debt obligations or future indebtedness.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need substantial additional funding in connection with our continuing operations. We expect our research and development expenses to continue to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. In addition, in connection with seeking and possibly obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

We expect that our existing unrestricted cash and cash equivalents and available-for-sale securities as of September 30, 2014 and anticipated cost sharing reimbursements under our license and collaboration agreement with Baxter related to MM-398 will enable us to fund operations into the second half of 2015. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our six most advanced product candidates;
- the success of our collaborations with Baxter and PharmaEngine related to MM-398 and any future collaborations with other parties that we may enter into;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- · the costs of commercialization activities, including product sales, marketing, manufacturing and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;

- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to establish and maintain commercial manufacturing arrangements for the manufacture of drug product on behalf of third-party pharmaceutical companies; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available until 2015 at the earliest, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external source of funds, other than under our collaboration with Baxter for the development and commercialization of MM-398, which is terminable by Baxter for convenience upon 180 days' prior written notice, our collaboration with Sanofi, which we have agreed with Sanofi will terminate effective December 17, 2014 unless we choose to accelerate such termination date, and under our development, license and supply agreement with Actavis, which is terminable by Actavis for convenience in specified circumstances upon 90 days' prior written notice. Other sources of funds may not be available or, if available, may not be available on terms satisfactory to us and could result in significant stockholder dilution. On July 17, 2013, we sold an aggregate of 5,750,000 shares of our common stock at a price to the public of \$5.00 per share and issued \$125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020 in concurrent underwritten public offerings. Furthermore, on March 4, 2014, we filed a registration statement on Form S-3 with the SEC to facilitate the issuance of our securities from time to time in one or more offerings of up to \$200,000,000 in the aggregate.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and these covenants may also require us to attain certain levels of financial performance and we may not be able to do so; any such failure may result in the acceleration of such debt and the foreclosure by our creditors on the collateral we used to secure the debt. The debt issued in a debt financing would also be senior to our outstanding shares of capital stock, and may rank equally with or senior to the convertible senior notes upon our liquidation. Our existing indebtedness and the pledge of our assets as collateral limit our ability to obtain additional debt financing. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our investments are subject to risks that could result in losses.

We invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate bonds, including commercial paper, and money market instruments. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities.

Risks Related to the Development and Commercialization of Our Product Candidates

We depend heavily on the success of our six most advanced product candidates. All of our product candidates are still in preclinical and clinical development. Clinical trials of our product candidates may not be successful. If we are unable to commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the acquisition of rights to MM-398 and the development of our five other most advanced product candidates for the treatment of various types of cancer. All of our therapeutic product candidates are still in preclinical and clinical development. Our ability to generate product revenues, which we do not expect will occur until 2015 at the earliest, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates. The success of our product candidates, which include both our therapeutic product candidates and companion diagnostic candidates, will depend on several factors, including the following:

- successful enrollment in, and completion of, preclinical studies and clinical trials;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States for our product candidates, including our companion diagnostics;
- establishing commercial manufacturing capabilities, either by building such facilities ourselves or making arrangements with third-party manufacturers;
- launching commercial sales of any approved products, whether alone or in collaboration with others;
- acceptance of any approved products by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of any products following approval; and
- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and successful interim results of a clinical trial do not necessarily predict successful final results.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all:
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding of a lack of clinical response or a finding that the patients are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates, companion diagnostics or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

For example, in a Phase 2 clinical trial of MM-121 in patients with non-small cell lung cancer, two of the three cohorts (Groups A and C) failed to meet their primary endpoints, and the third cohort (Group B) did not pass its planned interim analysis and ceased enrolling patients. Additionally, we did not meet the primary endpoints in our Phase 2 clinical trials of MM-121 in patients with ovarian cancer or in patients with breast cancer, although our ongoing biomarker analysis in each trial identified a potential subpopulation of patients benefiting from MM-121 in combination with either paclitaxel or exemestane, respectively.

Preclinical and clinical data may not be predictive of the success of later clinical trials, and are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the product is distributed or used; or
- be unable to obtain reimbursement for use of the product.

In particular, it is possible that the FDA and other regulatory agencies may not consider the results of our Phase 3 clinical trial of MM-398 for the treatment of patients with metastatic pancreatic cancer to be sufficient for approval of MM-398 for this indication. In general, the FDA suggests two adequate and well-controlled clinical trials to demonstrate effectiveness because a conclusion based on two persuasive studies will be more secure. Although the FDA informed us that the original design of our Phase 3 clinical trial of MM-398, plus supportive Phase 2 clinical trial data obtained to date, could potentially provide sufficient safety and effectiveness data for the treatment of patients with metastatic pancreatic cancer, the FDA has further advised us that whether one or two adequate and well controlled clinical trials will be required will be a review issue in connection with an NDA submission. Even with favorable results in our Phase 3 clinical trial, the FDA may nonetheless require that we conduct additional clinical trials, possibly using a different design.

Delays in testing or approvals may result in increases to our product development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to commercialize our product candidates and may harm our business and results of operations.

If serious adverse or undesirable side effects are identified during the development of our product candidates, we may need to abandon our development of some of our product candidates.

All of our product candidates are still in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Currently marketed therapies for solid tumors are

generally limited to some extent by their toxicity. Use of our product candidates as monotherapies in clinical trials also has resulted in adverse events consistent in nature with other marketed therapies. When used in combination with other marketed or investigational therapies, our product candidates may exacerbate adverse events associated with the other therapy. If our product candidates, either alone or in combination with other therapies, result in undesirable side effects or have characteristics that are unexpected, we may need to modify or abandon their development.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. In addition, many of our competitors have ongoing clinical trials for product candidates that could be competitive with our product candidates. Patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates or rely upon treatment with existing therapies that may preclude them from eligibility for our clinical trials.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

In general, we forecast enrollment for our clinical trials based on experience from previous clinical trials and monitor enrollment to be able to make adjustments to clinical trials when appropriate, including as a result of slower than expected enrollment that we experience from time to time in our clinical trials. For example, we experienced slower than expected enrollment in our Phase 2 clinical trial of MM-121 in combination with exemestane for hormone receptor positive breast cancer. In response, we revised the entry criteria for the clinical trial to correspond with changes in clinical practice and also expanded the number of sites and countries participating in the clinical trial. It is possible that slow enrollment in other clinical trials in the future could require us to make similar adjustments. If these adjustments do not overcome problems with slow enrollment, we could experience significant delays or abandon the applicable clinical trial altogether.

If we are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our therapeutics.

An important component of our business strategy is to develop, either alone or together with third parties, *in vitro* or *in vivo* companion diagnostics for each of our therapeutic product candidates. There has been limited success to date industry-wide in developing companion diagnostics, in particular *in vitro* companion diagnostics. To be successful, we will need to address a number of scientific, technical, regulatory and logistical challenges.

Although we have developed prototype assays for some *in vitro* diagnostic candidates, all of our companion diagnostic candidates are in preclinical development or clinical feasibility testing. We have limited experience in the development of diagnostics and may not be successful in developing appropriate diagnostics to pair with any of our therapeutic product candidates that receive marketing approval. The FDA and similar regulatory authorities outside the United States are generally expected to regulate *in vitro* companion diagnostics as medical devices and *in vivo* companion diagnostics as drugs. In each case, companion diagnostics require separate regulatory approval prior to commercialization. Given our limited experience in developing diagnostics, we expect to rely in part on third parties for their design,

development and manufacture. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostics for our therapeutic product candidates, or experience delays in doing so, the development of our therapeutic product candidates may be adversely affected, our therapeutic product candidates may not receive marketing approval and we may not realize the full commercial potential of any therapeutics that receive marketing approval. As a result, our business would be harmed, possibly materially.

Even if any of our product candidates, including our six most advanced product candidates, receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates, including our six most advanced product candidates, receive marketing approval, they may nonetheless not gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors that may be uncertain or subjective, including:

- the prevalence and severity of any side effects;
- efficacy and potential advantages or disadvantages compared to alternative treatments;
- · the price we charge for our product candidates;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- our ability to successfully develop companion diagnostics that effectively identify patient populations likely to benefit from treatment with our therapeutic products;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. For MM-398, subject to approval by the applicable regulatory authorities, we intend to market and sell MM-398 in the United States, while we expect that Baxter and PharmaEngine will market and sell MM-398 in the rest of the world. Our commercialization plans for our other therapeutic candidates will depend in part on any future collaborations into which we may enter.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We also may not be successful entering into arrangements with third parties to sell and market our product candidates or doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new therapeutic and diagnostic products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Several large pharmaceutical and biotechnology companies currently market and sell products for the treatment of the solid tumor indications for which we are developing our product candidates. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

We are developing our product candidates for the treatment of solid tumors. There are a variety of available therapies marketed for solid tumors. In many cases, these drugs are administered in combination to enhance efficacy. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis, including the active ingredients in MM-398 and MM-302. Many of these approved drugs are well established therapies and are widely accepted by physicians, patients and third-party payors. This may make it difficult for us to achieve our business strategy of replacing existing therapies with our product candidates.

There are also a number of products in late stage clinical development to treat solid tumors. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic and diagnostic products vary widely from country to country. Some countries require approval of the sale

price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment 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, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for any product candidates or products that we may develop;

- injury to our reputation and significant negative media attention;
- · withdrawal of patients from clinical trials;
- significant costs to defend the related litigation;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold \$10.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any or every liability that may arise.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

We have based our research and development efforts on our Network Biology approach. Notwithstanding our large investment to date and anticipated future expenditures in Network Biology, we have not yet developed, and may never successfully develop, any marketed products using this approach. As a result of pursuing our Network Biology approach, we may fail to address or develop product candidates or indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success.

We also may not be successful in our efforts to identify or discover additional product candidates through our Network Biology approach. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have otherwise been more advantageous for us to retain sole development and commercialization rights.

We plan to establish separately funded companies for the development of product candidates using our Network Biology approach in some areas outside the oncology field. These companies may not be successful in the development and commercialization of any product candidates.

We plan to apply our Network Biology approach to multiple additional disease areas outside the oncology field. We expect to do so in some cases through the establishment of separately funded companies. For example, we established Silver Creek to develop product candidates in the field of regenerative medicine using Network Biology. Silver Creek has received separate funding from investors other than us. Although Silver Creek is currently majority owned by us, in the future we may not be the

majority owner of or control Silver Creek or other companies that we establish. If in the future we do not control Silver Creek or any future similar company that we establish, Silver Creek or such other companies could take actions that we do not endorse or with which we disagree, such as using Network Biology in a way that reflects adversely on us. In addition, these companies may have difficulty raising additional funds and could encounter any of the risks in developing and commercializing product candidates to which we are subject.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We also store certain low level radioactive waste at our facilities until the materials can be properly disposed of. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological, hazardous or radioactive materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Fluctuations in foreign currency exchange rates could substantially increase the costs of our clinical trial programs.

A significant portion of our clinical trial activities are conducted outside of the United States, and associated costs may be incurred in the local currency of the country in which the trial is being conducted, which costs could be subject to fluctuations in foreign exchange rates. At present, we do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in geographies in which we conduct clinical trials could have a negative impact on our research and development costs. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our development costs.

Risks Related to Our Dependence on Third Parties

The successful development and commercialization of MM-398 depends substantially on our collaboration with Baxter. If Baxter is unable or unwilling to further develop or commercialize MM-398, or experiences significant delays in doing so, our business will be materially harmed.

In September 2014, we entered into a license and collaboration agreement with Baxter for the development and commercialization of MM-398. Prior to this collaboration, we did not have a history of working together with Baxter. The collaboration involves a complex allocation of rights, provides for

milestone payments to us based on the achievement of specified development, regulatory and commercial sale milestones, and provides us with royalty-based revenue if MM-398 is successfully commercialized. We cannot predict the success of the collaboration.

Under our license and collaboration agreement, Baxter has significant control over the conduct and timing of development and commercialization efforts with respect to MM-398 outside of the United States. We have little control over the amount, timing and quality of resources that Baxter devotes to the development or commercialization of MM-398 outside of the United States. If Baxter fails to devote sufficient financial and other resources to the future development or commercialization of MM-398 outside of the United States would be delayed or could fail. This would result in a delay in our receiving milestone payments or royalties with respect to MM-398 outside of the United States or in our not receiving such milestone payments or royalties at all.

If we lose Baxter as a collaborator in the development or commercialization of MM-398, our business will be materially harmed.

Baxter has the right to terminate our agreement for the development and commercialization of MM-398, in whole or with respect to specified territories, at any time and for any reason, upon 180 days' prior written notice. Baxter also has the right to terminate our agreement if we fail to cure a material breach of our agreement within a specified cure period, or fail to diligently pursue a cure if such a breach is not curable within such period.

If Baxter terminates our agreement at any time, whether on the basis of our uncured material breach or for any other reason, it would delay or prevent our further development of MM-398 and materially harm our business and could accelerate our need for additional capital. In particular, we would have to fund the future clinical development and commercialization of MM-398 outside of the United States on our own, seek another collaborator or licensee for such clinical development and commercialization, or abandon the development and commercialization of MM-398.

The successful development and commercialization of MM-121 depends substantially on continued assistance from Sanofi during the period leading up to the termination of our collaboration. If Sanofi is unable or unwilling to effect a smooth transition, or disagrees with us about its responsibilities in such termination, our business will be materially harmed.

MM-121 is one of our most clinically advanced product candidates. In September 2009, we entered into a license and collaboration agreement with Sanofi for the development and commercialization of MM-121. On June 17, 2014, we and Sanofi agreed to terminate the collaboration effective December 17, 2014 unless we choose to accelerate such termination date. Because the collaboration involves a complex allocation of rights and responsibilities between us and Sanofi, we will rely on Sanofi to provide certain information, rights and material during the period leading up to the effective termination date of the collaboration, including the reimbursement for MM-121 development costs that we incur through such date.

If Sanofi refuses to reimburse development costs through the effective date of termination of the license and collaboration agreement, disagrees with us about its other responsibilities with respect to the termination, or otherwise encumbers the termination of the collaboration, it would delay or prevent our development of MM-121 and materially harm our business and could accelerate our need for additional capital. In particular, we would have to fund the clinical development and commercialization of MM-121 on our own sooner than anticipated, seek another collaborator or licensee for such clinical development and commercialization, or abandon the development and commercialization of MM-121.

We may depend on collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

Depending on our capital requirements, development and commercialization costs, need for additional therapeutic expertise and other factors, it is possible that we will enter into additional development and commercialization arrangements with respect to either oncology product candidates or product candidates in other therapeutic areas. In particular, while we expect to apply our Network Biology approach to other disease areas through arrangements similar to Silver Creek, it is also possible that we will seek to enter into licensing agreements or other types of collaborations for the application of our Network Biology approach.

Our likely collaborators for any distribution, marketing, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Under the Baxter agreement, we granted Baxter a right of first negotiation to obtain a license to develop and commercialize MM-111, MM-141 and MM-302 outside of the United States. Baxter's right of first negotiation could discourage other companies from engaging with us in discussions or negotiations regarding potential collaboration, partnership or similar agreements.

We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates, including our collaborations with Baxter and with Sanofi, which will terminate effective December 17, 2014 unless we choose to terminate it earlier, pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product
 candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under
 terms that are more economically attractive;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- disputes may arise between us and the collaborators that result in the delay or termination of the research, development or commercialization of
 our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish additional collaborations, we may have to alter our development plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory agencies require us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that adverse event data are reported within required timeframes, that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We also rely on other third parties to store and distribute supplies for our clinical trials. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval of our product candidates or commercialization of our products or cause us to incur additional costs, producing additional losses and depriving us of potential product revenue.

We also intend to utilize companion diagnostics in several of our planned clinical trials, including planned clinical trials of MM-121 and MM-141, to preselect patients who will receive specified treatment regimens. We will rely on third party laboratories to test patient samples in connection with such companion diagnostics. Any failure on the part of these laboratories to properly perform such testing could jeopardize those clinical trials and delay or prevent the approval of the associated therapeutic candidate.

Risks Related to the Manufacturing of Our Product Candidates

We have limited experience in manufacturing our product candidates. We will need to upgrade and expand our manufacturing facility and augment our manufacturing personnel and processes in order to meet our business plans. If we fail to do so, we may not have sufficient drug product to meet our clinical development and commercial requirements.

We have a manufacturing facility located at our corporate headquarters in Cambridge, Massachusetts. We manufacture drug substance at this facility that we use for research and development purposes and for clinical trials of our product candidates. We do not have experience in manufacturing products at a commercial scale. Our current facility may not be sufficient to permit manufacturing of our product candidates for Phase 3 clinical trials or commercial sale. In order to meet our business plan, which contemplates our internally manufacturing drug substance for most of our clinical trials and, over the long-term, for a significant portion of our commercial requirements, we will need to upgrade and expand our manufacturing facilities, add manufacturing personnel and ensure that validated processes are consistently implemented in our facilities. The upgrade and expansion of our facilities will require additional regulatory approvals. In addition, it will be costly and time-consuming to expand our facilities and recruit necessary additional personnel. If we are unable to expand our facilities in compliance with regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including in obtaining regulatory approvals of our product candidates, which could materially damage our business and financial position.

If our manufacturing facility is damaged or destroyed or production at this facility is otherwise interrupted, our business and prospects would be negatively affected.

If the manufacturing facility at our corporate headquarters or the equipment in it is damaged or destroyed, we may not be able to quickly or economically replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of this facility or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need FDA approval before selling any products manufactured at that facility. Such an event could delay our clinical trials or, if our product candidates are approved by the FDA, reduce our product sales.

Currently, we maintain insurance coverage against damage to our property and equipment and to cover business interruption and research and development restoration expenses. If we have underestimated our insurance needs with respect to an interruption in our clinical manufacturing of our product candidates, we may not be able to cover our losses.

Any other interruption of production at our manufacturing facility also could damage our business. For example, in 2009, we experienced a viral contamination at this facility that required that we

shut the facility entirely for decontamination. Because of this contamination, the FDA placed a partial clinical hold on our investigational new drug application for MM-121 until we submitted supporting documentation to the FDA regarding our decontamination procedures. Although we were able to resolve this issue, with the FDA lifting the partial clinical hold in April 2010, other companies have experienced similar contamination problems, and we could experience a similar problem in the future that is more difficult to resolve and could lead to a clinical hold.

We expect to continue to contract with third parties for at least some aspects of the production of our product candidates for clinical trials and for our products if they are approved for marketing. This increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third-party manufacturers for some aspects of the production of our product candidates for preclinical testing and clinical trials, including the production of MM-121 and fill-finish and labeling activities for all our product candidates. In addition, while we believe that our existing manufacturing facility, or additional facilities that we will be able to build, will be sufficient to meet our requirements for manufacturing a significant portion of drug substance for our research and development activities, we may need to rely on third-party manufacturers for some of these requirements, particularly later stage clinical trials of our antibody product candidates, and, at least in the near term, for commercial supply of any product candidates for which we obtain marketing approval.

In connection with the termination of our license and collaboration agreement with Sanofi for the development and commercialization of MM-121, we expect to assume responsibility for the manufacture of MM-121 by assuming an agreement with a third-party manufacturer. Other than the commercial supply agreement that we intend to enter into with Baxter and under which we will supply bulk MM-398 drug substance, we do not have any other agreements with third-party manufacturers for the clinical or commercial supply of any of our product candidates, and we may be unable to conclude such agreements or to do so on acceptable terms. Reliance on third-party manufacturers entails additional risks, including:

- · reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- · the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, or Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. Because there are a limited number of manufacturers that operate under cGMP or QSR regulations and that might be capable of manufacturing for us, we may not have access to such manufacturers.

We currently rely on single suppliers for the resins, media and filters that we use for our manufacturing process. We purchase these materials from our suppliers on a purchase order basis and do not have long-term supply agreements in place. Any performance failure or refusal to supply on the part

of our existing or future suppliers could delay clinical development, marketing approval or commercialization of our products. If our current suppliers cannot perform as agreed, we may be required to replace one or more of these suppliers. Although we believe that there may be a number of potential long-term replacements to each supplier, we may incur added costs and delays in identifying and qualifying any such replacements.

We likely will rely upon third-party manufacturers to provide us with necessary reagents and instruments to develop, test and manufacture our *in vitro* companion diagnostics. Currently, many reagents are marketed as Research Use Only, or RUO, products under FDA regulations. In June 2011, the FDA issued a draft guidance that outlined the FDA's intention to impose additional restrictions on the provision of RUO products. If this guidance is finalized as drafted, we may experience difficulty securing the reagents that we need.

Our potential future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

We rely on third parties to perform various tasks related to the manufacturing of our product candidates. Compliance by such third parties with regulations of the FDA or other regulatory bodies cannot be assured, which could adversely impact our clinical trials.

A former fill-finish third-party contractor that we used to fill and package both MM-121 and MM-111 experienced FDA inspection issues with its quality control processes that resulted in a formal warning letter from the FDA. Following a review by Sanofi and us, some MM-121 was pulled from clinical trial sites and replaced with MM-121 that was filled by a different contractor. This restocking resulted in a few patients missing one or two doses of MM-121.

The MM-111 that was being used in our clinical trials was also filled and packaged by this same contractor. The FDA inquired about the effect of this contractor's quality issues on MM-111 clinical trial materials. Following our response to the FDA's inquiry, the FDA requested in January 2012 that we obtain new consents from any patients enrolled in our ongoing Phase 1 clinical trials of MM-111 in connection with continued use in these trials of MM-111 material filled and packaged by this contractor. In addition, the FDA placed a partial clinical hold on these ongoing clinical trials, which restricted our ability to enroll new patients in these trials, until MM-111 material filled and packaged by a new third-party contractor that we engaged was available. This restocking is complete and resulted in a short delay in the dosing of a few patients without any patients missing a dose.

Although we have addressed the concerns of the FDA with respect to the clinical trial material filled and packaged by our former third-party contractor, it is possible that we could experience similar issues with other contractors.

Risks Related to Our Intellectual Property

If we fail to fulfill our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements with third parties, including with respect to MM-121, MM-111, MM-302, MM-151 and MM-141, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The occurrence of such events could materially harm our business.

If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. 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. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Under the America Invents Act enacted in 2011, the United States moved to this first to file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. We may become involved in opposition, interference or derivation proceedings challenging our patent rights or the patent rights of others. An adverse determi

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability,

and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to initiate infringement lawsuits, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the enforceable proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We are currently engaged in an opposition proceeding in the European Patent Office. If we are not successful in this proceeding, we may not be able to commercialize MM-111 without infringing patents held by third parties.

We are currently engaged in an opposition proceeding in the European Patent Office to narrow or invalidate the claims of a European patent owned by a third party. For more information, see Part II, Item 1. Legal Proceedings in this Quarterly Report on Form 10-Q. We have obtained a favorable interim decision in this opposition, although that decision is now under appeal. The ultimate outcome of this opposition remains uncertain. If we are not ultimately successful in this proceeding and the issued claims of the patent we are opposing is determined to be valid and construed to cover MM-111, we may not be able to commercialize MM-111 in some or all European countries without infringing such patents. If we infringe a valid claim of this patent, we would need to obtain a license to the patented technology, which may cause us to incur licensing-related costs. However, a license to the patent that is the subject of the opposition proceeding may not be available on commercially reasonable terms or at all. As a result, we could be liable for monetary damages or we may be forced to delay, suspend, forego or cease commercializing MM-111 in some or all countries in Europe if we were found to infringe a valid claim of the patent. In addition, even if we are ultimately successful in this opposition proceeding, such result would be limited to our activities in Europe.

We are also aware of issued or pending counterparts to one of these European patents in the United States that may be relevant to our development and commercialization of MM-121. If these patents were determined to be valid and construed to cover MM-121, our development and commercialization of MM-121 in the United States could be delayed or prevented.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to our patented technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. In addition, any of these parties may breach the agreements and disclose our

proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Regulatory Approval of Our Product Candidates

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates, including our six most advanced product candidates, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, import, export, sampling and marketing are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the FDA and other regulatory agencies for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA or other regulatory agencies. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based on a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, changes in regulatory review for each submitted product application or approval of other products for the same indication may cause delays in the approval or rejection of an application. Regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we pursue development of a companion diagnostic to identify patients who are likely to benefit from a therapeutic product, failure to obtain approval for the diagnostic may prevent or delay approval of the therapeutic product.

We are attempting to develop companion diagnostics to identify patients who are likely to benefit from our therapeutic product candidates. We currently rely on and expect to continue to rely on third parties for much of the development, testing and manufacturing of our companion diagnostics, and will likely rely on such third parties to also obtain any required regulatory approval for and then commercially supply such companion diagnostics. All of our companion diagnostic candidates are in preclinical development or clinical feasibility testing. We have very limited experience in the development of diagnostics and, even with the help of third parties with greater experience, may fail to obtain the required diagnostic product marketing approval, which could prevent or delay approval of the therapeutic product.

In July 2011, the FDA issued draft guidance that stated that if safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will not approve the therapeutic unless the FDA approves or clears this "*in vitro* companion diagnostic device" at the same time that the FDA approves the therapeutic. The approval or clearance of the *in vitro* diagnostic most likely will occur through the FDA's Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health. It is unclear whether the FDA will finalize this guidance in its current format. Even if the FDA does finalize the guidance in its current format, it is unclear how it will interpret the guidance. Even with the issuance of the draft guidance, the FDA's expectations for *in vitro* companion diagnostics remain unclear in some respects. The FDA's developing expectations will affect our *in vitro* companion diagnostics. In particular, the FDA may limit our ability to use retrospective data, otherwise disagree with our approaches to trial design, biomarker qualification, clinical and analytical validity and clinical utility, or make us repeat aspects of the trial or initiate new trials.

Because our companion diagnostic candidates are at an early stage of development, we cannot yet know what the FDA will require for any of these tests. For four of our six most advanced product candidates, MM-121, MM-111, MM-151 and MM-141, we are attempting to develop an *in vitro* companion diagnostic that will help identify patients likely to benefit from the therapy. Whether the FDA will consider these *in vitro* diagnostics to be "*in vitro* companion diagnostic devices" that require simultaneous approval or clearance with the therapeutics under the draft guidance will depend on whether the FDA views the diagnostics to be essential to the safety and efficacy of these therapeutics.

For our two other most advanced product candidates, MM-398 and MM-302, although we are also investigating possible *in vitro* companion diagnostics, we are currently developing *in vivo* companion diagnostics in the form of imaging agents that may help identify patients likely to benefit from the therapy. Imaging agents are regulated as drugs by the FDA's Center for Drug Evaluation and Research and, as such, are generally subject to the regulatory requirements applicable to other new drug candidates. Although the FDA has not issued guidance with respect to the simultaneous approval of *in vivo* diagnostics and therapeutics, it is possible that the FDA will apply a standard similar to that for *in vitro* diagnostics.

Based on the FDA's past practice with companion diagnostics, if we are successful in developing a companion diagnostic for any of our six most advanced product candidates, we would expect that FDA approval of an *in vitro* companion diagnostic, and possibly an *in vivo* companion diagnostic, would be required for approval and subsequent commercialization of each such therapeutic product candidate. We are not aware of any currently available diagnostics that, if necessary, would otherwise allow us to proceed with the approval and subsequent commercialization of our product candidates despite a delay in or failure of our attempts to develop companion diagnostics.

Because we expect to rely on third parties for various aspects of the development, testing and manufacture, as well as for regulatory approval for and commercial supply, of our companion diagnostics, the commercial success of any of our product candidates that require a companion diagnostic will be tied to and dependent on the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies.

If we fail to maintain orphan drug exclusivity for MM-398, MM-111 or MM-141, we will have to rely on other rights and protections for these product candidates.

We have obtained orphan drug designation in the United States and orphan medicinal product designation in the European Union for MM-398 for the treatment of pancreatic cancer and have obtained orphan drug designation in the United States for MM-111 for the treatment of esophageal, gastric and

gastroesophageal junction cancers and for MM-141 for the treatment of pancreatic cancer. In the United States, under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

In the United States, the company that first obtains FDA approval for a designated orphan drug for the specified rare disease or condition receives orphan drug marketing exclusivity for that drug for a period of seven years. This orphan drug exclusivity prevents the FDA from approving another application, including a full NDA, to market the same drug for the same orphan indication, except in limited circumstances. For purposes of small molecule drugs, the FDA defines the term "same drug" to mean a drug that contains the same active molecule and that is intended for the same use as the approved orphan drug. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

The European Medicines Agency, or EMA, grants orphan medicinal product designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the European Union. Orphan medicinal product designation from the EMA provides ten years of marketing exclusivity following drug approval, subject to reduction to six years if the designation criteria are no longer met.

Our therapeutic product candidates for which we intend to seek approval as biological or drug products may face competition sooner than expected.

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Health Care and Education Reconciliation Act of 2010, or the Health Care Reform Law, an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on their similarity to existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a biologics license application, or BLA. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of our products approved as a biological product under a BLA should qualify for the 12 year period of exclusivity. However:

- a potential competitor could seek and obtain approval of its own BLA during our exclusivity period instead of seeking approval of a biosimilar version; and
- the FDA could consider a particular product candidate, such as MM-302, which contains both drug and biological product components, to be a drug subject to review pursuant to an NDA, and therefore eligible for a significantly shorter marketing exclusivity period as provided under the Drug Price Competition and Patent Term Restoration Act of 1984.

Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, a drug product approved under an NDA, such as MM-398 if it were to be approved, could face generic competition earlier than expected. The enactment of the Generic Drug User Fee Amendments of 2012 as part of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, established a user fee program that will generate hundreds of millions of dollars in funding for the FDA's generic drug review program. Funding from the user fee program, along with performance goals that the FDA negotiated with the generic drug industry, could significantly decrease the timeframe for FDA review and approval of generic drug applications.

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

We intend to market our products, either ourselves or with partners, both within and outside the United States. This may increase the risks described below with respect to our compliance with foreign regulations.

In order to market and sell our products in the European Union and many other jurisdictions, we or our partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing, including sometimes additional testing in children. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our partners may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We or our partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP or QSR requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

· restrictions on such products, manufacturers or manufacturing processes;

- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- · recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- · product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDASIA provides the FDA with new inspection authorities. A drug or biologic will be considered adulterated, with possible resulting civil and criminal penalties, if the owner or operator of the establishment where it is made, processed, packed or held delays, denies, limits or refuses inspection. The FDASIA also replaces the biennial inspection schedule for drugs and biologics with a risk-based inspection schedule. The law grants the FDA authority to require a drug or biologics manufacturer to provide, in advance or instead of an inspection, and at the manufacturer's expense, any records or other information that the agency may otherwise inspect at the facility. The FDASIA also permits the FDA to share inspection information with foreign governments under certain circumstances. The FDASIA is complex and has yet to be fully interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

The FDASIA also provides the FDA with additional authority to exercise against manufacturers of drugs or biologics that are not adhering to pediatric study requirements, which apply even if the manufacturer is not seeking to market the drug or biologic to pediatric patients. As of April 2013, the FDA must issue non-compliance letters to companies who do not meet the pediatric study requirements. Any company receiving a non-compliance letter would have an opportunity to respond, and the non-compliance letter and company response would become publicly available.

Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

• the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

Moreover, in March 2010, President Obama signed into law the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the Health Care Reform Law until all applicable federal and state agencies have issued regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Most recently, on July 9, 2012, President Obama signed the FDASIA into law. The broad, sweeping law establishes new user fee programs and provides the FDA with new authority in the areas of drugs, biologics and medical devices. We are not certain what the full impact of these changes will be on our business, particularly as the FDA will need to publish regulations and issue guidances to implement the new legislation. We are not sure whether additional legislative changes will be enacted, or whether other FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In the area of companion diagnostics, FDA officials indicated in 2010 that the agency planned to issue two guidances in this area. The FDA issued one draft guidance in July 2011. The FDA has yet to issue a second draft guidance and may decide not to issue a second draft guidance. The FDA's expected issuance of a final guidance, or issuance of additional draft guidance, could affect our development of *in vitro* companion diagnostics and the applicable regulatory requirements. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our Chief Executive Officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Robert J. Mulroy, our President and Chief Executive Officer, and the other principal members of our executive and scientific teams. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our development, manufacturing, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We have entered into and may continue to enter into or seek to enter into business combinations and acquisitions which may be difficult to integrate, disrupt our business, divert management attention or dilute stockholder value.

As part of our business strategy, we may enter into business combinations and acquisitions. Although we acquired Hermes in October 2009, we have limited experience in making acquisitions. In addition, acquisitions are typically accompanied by a number of risks, including:

- the difficulty of integrating the operations and personnel of the acquired companies;
- the potential disruption of our ongoing business and distraction of management;
- potential unknown liabilities and expenses;
- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

If we are not successful in completing acquisitions that we may pursue in the future, we would be required to reevaluate our business strategy and we may have incurred substantial expenses and devoted significant management time and resources in seeking to complete the acquisitions. In addition, with future acquisitions, we could use substantial portions of our available cash as all or a portion of the purchase price. As we did for the acquisition of Hermes, we could also issue additional securities as consideration for these acquisitions, which could cause our stockholders to suffer significant dilution.

Risks Related to Our Common Stock

Our executive officers, directors and principal stockholders maintain the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially own a large portion of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, will significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could allow, delay or prevent an acquisition of our company on terms that other stockholders may desire.

Provisions in our corporate 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 corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. 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. Among others, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would
 work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of
 directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Further, the repurchase right under the convertible senior notes in connection with a fundamental change (as defined therein) and any increase in the conversion rate in connection with a make-whole fundamental change could also discourage a potential acquirer.

Our stock price has been and may in the future be volatile, which could cause holders of our common stock to incur substantial losses.

Our stock price has been and in the future may be subject to substantial price volatility. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders could incur substantial losses. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- · results of clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patents or other proprietary rights;
- the recruitment or departure of key personnel;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for holders of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for holders of our common stock for the foreseeable future.

We are currently an "emerging growth company" and our election to delay adoption of new or revised accounting standards applicable to public companies may result in our financial statements not being comparable to those of other public companies. As a result of this and other reduced disclosure requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are currently an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. Because the market value of our common stock held by non-affiliates

exceeded \$700 million as of June 30, 2014, we will cease to be an emerging growth company as of December 31, 2014. For so long as we remain an emerging growth company, however, we are permitted and intend to rely on exemptions from certain reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include but are not limited to not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Among other provisions, the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to delay such adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies. As a result of such election, our financial statements may not be comparable to the financial statements of other public companies.

We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Future sales of shares of our common stock, including by us or our directors and executive officers or shares issued upon the exercise of currently outstanding options and warrants, or upon conversion of outstanding convertible notes, could cause the market price of our common stock to drop significantly, even if our business is doing well.

A substantial portion of our outstanding common stock can be traded without restriction at any time. As a result of securities laws, a portion of our outstanding common stock is restricted but can be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, at any time. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, by us or others, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options and warrants, and we may issue shares of our common stock upon conversion of outstanding convertible notes. The exercise of these options and warrants or the issuance of shares of our common stock upon conversion of the notes and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We cannot predict the size of future issuances or the effect, if any, that any future issuances may have on the market price for our common stock.

Furthermore, on March 4, 2014, we filed a registration statement on Form S-3 with the SEC to facilitate the issuance of our securities from time to time in one or more offerings of up to \$200,000,000 in the aggregate. This registration statement was declared effective by the SEC on April 2, 2014. Any sale of additional shares of our common stock or other securities could reduce the market price of our common stock.

Item 5. Other Information.

On November 6, 2014, we entered into an amendment to the loan agreement with Hercules pursuant to which we and Hercules agreed to extend by an additional four months the period during which we make interest-only payments on our \$40.0 million principal term loan. As a result of the amendment, we will repay the aggregate outstanding principal balance of the loan in equal monthly installments of principal and interest (based on a 30 month amortization schedule) beginning on February 1, 2015. The remaining principal balance and interest will be due and payable on November 1, 2016.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

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.

MERRIMACK PHARMACEUTICALS, INC.

Date: November 10, 2014

By: /s/ William A. Sullivan

William A. Sullivan Chief Financial Officer and Treasurer

(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Description of Exhibit
License and Collaboration Agreement, dated as of September 23, 2014, by and among the Registrant, Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA
First Amendment to Assignment, Sublicense and Collaboration Agreement, dated as of September 22, 2014, by and between the Registrant and PharmaEngine, Inc.
Third Amendment to Loan and Security Agreement, dated as of November 6, 2014, by and between the Registrant and Hercules Technology Growth Capital, Inc.
Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
XBRL Instance Document
XBRL Taxonomy Extension Schema Document
XBRL Taxonomy Extension Calculation Linkbase Document
XBRL Taxonomy Extension Definition Linkbase Document
XBRL Taxonomy Extension Label Linkbase Database
XBRL Taxonomy Extension Presentation Linkbase Document

[†] Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

^{*} Filed herewith.

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

LICENSE AND COLLABORATION AGREEMENT

By and Among

BAXTER INTERNATIONAL INC.,

BAXTER HEALTHCARE CORPORATION,

BAXTER HEALTHCARE SA

and

MERRIMACK PHARMACEUTICALS, INC.

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LICENSE AND COLLABORATION AGREEMENT

This License and Collaboration Agreement (this "<u>Agreement</u>"), dated the 23rd day of September, 2014 (the "<u>Effective Date</u>"), is by and among BAXTER INTERNATIONAL INC., a company organized under the laws of Delaware with its principal place of business at One Baxter Parkway, Deerfield, IL 60015, US ("<u>BII</u>"), BAXTER HEALTHCARE CORPORATION, a company organized under the laws of Delaware with its principal place of business at One Baxter Parkway, Deerfield, IL 60015, US ("<u>BHC</u>"), and BAXTER HEALTHCARE SA, a company organized under the laws of Switzerland with its principal place of business at Postfach 8010, Zurich, Switzerland ("<u>BHSA</u>" and together with BII and BHC, "<u>BAXTER</u>"), on the one hand, and MERRIMACK PHARMACEUTICALS, INC., a Delaware corporation with its principal offices at One Kendall Square, Suite B7201, Cambridge, MA 02139, US ("<u>MERRIMACK</u>"), on the other hand.

INTRODUCTION

- 1. MERRIMACK has worldwide rights, excluding rights in Taiwan that are held by PharmaEngine (as defined below), to a nanoliposomal formulation of irinotecan, known as MM-398, as more specifically described below.
 - 2. BAXTER is engaged in the research, development, manufacture and commercialization of therapeutic products for various diseases and disorders.
- 3. BAXTER and MERRIMACK are interested in collaborating in the development of products comprising MM-398 and in entering into a licensing arrangement granting BAXTER certain rights as to such products in the Licensed Territory (as defined below) on the terms and conditions set forth herein.
- 4. In addition, MERRIMACK is interested in granting BAXTER a right of first negotiation related to the commercialization of certain additional compounds known as MM-111, MM-141 and MM-302.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt of which is hereby acknowledged, BAXTER and MERRIMACK agree as follows:

Article I Definitions

For purposes of clarity, when used in this Agreement, each of the following terms shall have the meanings set forth in this Article I:

Section 1.1 "<u>Affiliate</u>". Affiliate means, with respect to a Party, any Person that controls, is controlled by, or is under common control with such Party. For purposes of this Section 1.1, "control" shall refer to (a) in the case of a Person that is a corporate entity, direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such Person, or (b) in the case of a Person that is not a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

Section 1.2 "Bankruptcy Code". Bankruptcy Code means 11 U.S.C. §§ 101-1330 of the US Bankruptcy Code, as amended, and similar laws governing bankruptcy and insolvency in countries outside the US.

- Section 1.3 "BAXTER Intellectual Property". BAXTER Intellectual Property means, collectively, BAXTER Patent Rights and BAXTER Technology.
- Section 1.4 "BAXTER Patent Rights". BAXTER Patent Rights means all Patent Rights Controlled by BAXTER, itself or jointly with MERRIMACK, as of the Effective Date and thereafter during the Term that Cover any BAXTER Technology or the manufacture, use, offer for sale, sale or importation of the Licensed Compound or any Licensed Product.
- Section 1.5 "BAXTER Technology". BAXTER Technology means all Know-How Controlled by BAXTER, itself or jointly with MERRIMACK, as of the Effective Date and thereafter during the Term, that is used in, or necessary or useful for, the research, development, manufacture or Commercialization of the Licensed Compound or any Licensed Product.
- Section 1.6 "Business Day". Business Day means a day on which banking institutions in New York, New York, US are open for business, excluding any Saturday or Sunday.
 - Section 1.7 "China". China means the People's Republic of China.
 - Section 1.8 "CMO". CMO means a Third Party contract manufacturing organization.
- Section 1.9 "<u>Commercialization</u>". Commercialization means all activities related to the commercial exploitation of the Licensed Compound and/or the Licensed Products, including importation, exportation, marketing, promotion, distribution, pre-launch, launch, sale or offering for sale of any Licensed Product. When used as a verb, "Commercialize" or "Commercializing" means to engage in Commercialization.

Section 1.10 "Commercially Reasonable Efforts". Commercially Reasonable Efforts means, with respect to the performing Party, a level of efforts and resources, not less than reasonable efforts and resources, that is consistent with the efforts and resources that BAXTER or MERRIMACK, as applicable, typically devotes to its own internally discovered products, to which it solely owns all rights without financial obligations to any licensor, of similar market potential at a similar stage in the development or product life thereof, taking into account scientific and commercial factors, including issues of safety and efficacy, product profile, difficulty in developing or manufacturing the Licensed Compound or Licensed Product, competitiveness of alternative Third Party products in the marketplace, the patent or other proprietary position of the Licensed Compound or Licensed Product (including the ability to obtain or enforce, or have obtained or enforced, such patent or other proprietary positions), the regulatory requirements involved and the potential profitability, cost, market share, price or reimbursement to the performing Party of the Licensed Compound or Licensed Product marketed or to be marketed.

Section 1.11 "Companion Diagnostic". Companion Diagnostic means a diagnostic intended to assist physicians in making treatment decisions with respect to the use of the Licensed Compound or Licensed Product.

- Section 1.12 "Comparator Drug". Comparator Drug means unexpired comparator drugs used for Global Development Plan activities after the Effective Date.
- Section 1.13 "Conditional Approval". Conditional Approval means conditional approval of a Licensed Product by the EMA in accordance with Regulation (EC) No 507/2006, adopted on March 29, 2006.
- Section 1.14 "Confidential Information". Confidential Information means all Know-How or other confidential or proprietary information of a Party that is disclosed (whether in written, graphic, oral, electronic or other form) by or on behalf of such Party to the other Party pursuant to this Agreement, including information regarding a Party's or its licensor's technology, products, business, business plans, financial status, biological substances, chemical substances, formulations, techniques, methodology, equipment, sources of supply and patent positioning. The status, prospects or objectives regarding the Global Development Plan, Licensed Compound or Licensed Products shall be deemed "Confidential Information" of both Parties. All information disclosed prior to the Effective Date by or on behalf of either Party under, and subject to, the Mutual Confidential Disclosure Agreement, by and between MERRIMACK and Baxter Healthcare Corporation, dated June 18, 2013 and as amended July 28, 2014 (the "Confidentiality Agreement"), shall be deemed "Confidential Information" of the disclosing Party hereunder.
- Section 1.15 "<u>Control</u>" or "<u>Controlled</u>". Control or Controlled means with respect to any Know-How, Patent Right or other intellectual property right, the possession (whether by license (other than pursuant to this Agreement) or ownership, or control over an Affiliate with such a license or ownership) by a Party of the ability to grant to the other Party access or a license as provided herein without violating the terms of any agreement or arrangement with any Third Party existing before or after the Effective Date.
- Section 1.16 "<u>Cover"</u>, "<u>Covering"</u> or "<u>Covered</u>". Cover, Covering or Covered means, with respect to a Patent Right, that, but for a license granted to a Party under a Valid Claim included in such Patent Right (or, in the case of Joint Patent Rights, such Party's ownership interest in such Joint Patent Right), the practice by such Party of any invention claimed in such Patent Right would infringe such Valid Claim (or, in the case of a Valid Claim in a pending patent application, would infringe such Valid Claim if such pending patent application were to issue).
- Section 1.17 "<u>Development Costs</u>". Development Costs means, as to a Party, such Party's direct and identifiable internal and external costs of developing the Licensed Compound and Licensed Products in accordance with the Global Development Plan, consisting of the following:
- (a) with regard to a Party's internal costs and charges, Development Costs shall include all internal costs of such Party's personnel engaged in the development of the Licensed Compound and Licensed Products, at the [**] FTE Rate;

(b) with regard to a Party's external costs and charges, Development Costs shall consist of the actually incurred out-of-pocket costs and charges of suppliers of goods, including raw materials, and services, including contract research organizations, to the extent directly related to the development of the Licensed Compound and Licensed Products; and

(c) all internal and external costs associated with conducting clinical trials of the Licensed Compound and Licensed Products and all internal and external costs associated with the use of clinical supply of Licensed Product and any Comparator Drug in such trials, including the Manufacturing Cost of such clinical supply as described in Section 3.5.

Section 1.18 "<u>Drug Approval Application</u>". Drug Approval Application means an application submitted to a Regulatory Authority for Marketing Authorization required before commercial sale or use of (a) a pharmaceutical product as a drug in a regulatory jurisdiction or country and shall include a New Drug Application ("<u>NDA</u>") filed with the FDA, or any successor applications or procedures, (b) any non-US equivalent of a NDA, and (c) all supplements and amendments that may be filed with respect to the foregoing.

Section 1.19 "Drug Product". Drug Product means Licensed Product in bulk form, excluding any final packaging, finishing and labeling.

Section 1.20 "<u>Electronic BAXTER Data Management Standards</u>". Electronic BAXTER Data Management Standards means a document management system that encompasses tools (templates) for authoring, reviewing and approving submission content, publishing and archiving that meets 21 C.F.R. Part 11 requirements.

Section 1.21 "EMA". EMA means the European Medicines Agency or any successor agency thereof.

Section 1.22 "<u>EU</u>". EU means the European Union, as it may be constituted from time to time.

Section 1.23 "Executive Officers". Executive Officers mean the Chief Executive Officer of BAXTER (or a senior executive officer of BAXTER who is not a JSC member designated by BAXTER's Chief Executive Officer) and the Chief Executive Officer of MERRIMACK (or a senior executive officer of MERRIMACK who is not a JSC member designated by MERRIMACK's Chief Executive Officer).

Section 1.24 "FDA". FDA means the US Food and Drug Administration or any successor agency thereto.

Section 1.25 "Field". Field means all therapeutic, prophylactic and palliative uses in all possible indications.

Section 1.26 "First Commercial Sale". First Commercial Sale means, with respect to a given Licensed Product in a given country, the date on which such Licensed Product is first sold following Marketing Authorization of such Licensed Product in such country (or, in a country in which no Marketing Authorization is required, the date on which the Licensed Product is first sold) by, on behalf of or under the authority of BAXTER or any of BAXTER's Affiliates or sublicensees in arm's-length transactions to Third Parties (but not including sales relating to transactions among BAXTER and BAXTER's Affiliates and sublicensees and agents unless such Person is the end user thereof).

- Section 1.27 "First Indication". First Indication means the treatment of [**].
- Section 1.28 "Freedom to Operate Opinions". Freedom to Operate Opinions means all outside legal counsel opinions as to non-infringement.
- Section 1.29 "<u>FTE</u>". FTE means a full time equivalent person year (consisting of a total of [**] hours per year) of scientific or technical work or scientific or technical managerial work on or directly related to activities undertaken by a Party hereunder.
- Section 1.30 "FTE Rate". FTE Rate means, with respect to manufacturing technology transfer activities under this Agreement, [**] Dollars (US\$[**]) per FTE (as increased or decreased as set forth below, the "[**] FTE Rate"), and with respect to all other activities under this Agreement, [**] Dollars (US\$[**]) per FTE (as increased or decreased as set forth below, the "[**] FTE Rate"). Each such FTE Rate shall be increased or decreased annually on January 1 of each year, commencing with January 1, 2016, by the percentage increase or decrease in the Consumer Price Index ("CPI") as of the then-most-recent December 31 over the CPI as of the preceding December 31. As used in this Section 1.30, Consumer Price Index or CPI means the Consumer Price Index Urban Wage Earners and Clerical Workers, US City Average, All Items, 1982-84 = 100, published by the US Department of Labor, Bureau of Labor Statistics (or its successor equivalent index).
- Section 1.31 "Global Development Plan". Global Development Plan means the global development plan for the preclinical, clinical and other research, development, regulatory and pre-commercial manufacturing activities of the Parties directed to the Licensed Compound and any Licensed Product, as such plan is agreed upon, updated and amended from time to time in accordance with this Agreement. The initial Global Development Plan is attached to this Agreement as Exhibit A (the "Initial Global Development Plan").
- Section 1.32 "<u>Global Marketing and Commercialization Principles</u>". Global Marketing and Commercialization Principles means the global marketing and Commercialization principles for the Licensed Compound and any Licensed Product which shall address global product positioning, branding and Commercialization.
- Section 1.33 "IND". IND means an application submitted to a Regulatory Authority to initiate human clinical trials, including (a) an Investigational New Drug Application or any successor application or procedure filed with the FDA, (b) any non-US equivalent of a US Investigation New Drug Application, and (c) all supplements and amendments that may be filed with respect to the foregoing.

Section 1.34 "Joint Patent Rights". Joint Patent Rights means all Patent Rights that Cover any Joint Technology.

Section 1.35 "<u>Joint Technology</u>". Joint Technology means Know-How that is developed by one or more employees, agents or consultants of MERRIMACK on the one hand, and one or more employees, agents or consultants of BAXTER, on the other hand, in the performance of this Agreement.

Section 1.36 "Know-How". Know-How means any technical, scientific and business information, data and materials, including all biological, chemical, pharmacological, toxicological, preclinical, clinical, and assay information, data and materials, analyses, ideas, discoveries, inventions, methods, techniques, improvements, concepts, designs, processes, procedures, compositions, plans, formulae, specifications and trade secrets, whether or not patentable, including documents and other media (including paper, notebooks, books, files, ledgers, records, tapes, discs, diskettes, CD-ROM, trays and containers and any other media developed following the Effective Date) containing or storing any of the foregoing.

Section 1.37 "Knowledge of MERRIMACK Management". Knowledge of MERRIMACK Management means the knowledge of Seth Fidel, Fazal Khan, Peter Laivins, Gavin MacBeath, William McClements, Robert Mulroy, Jeffrey Munsie, Ulrik Nielsen, Birgit Schoeberl, Edward Stewart and William Sullivan.

Section 1.38 "<u>Laws</u>". Laws means all laws, statutes, rules, regulations, orders, judgments or ordinances having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision.

Section 1.39 "Licensed Asian Territory". Licensed Asian Territory means all Asian countries except for Taiwan.

Section 1.40 "Licensed Compound". Licensed Compound means MM-398.

Section 1.41 "Licensed Intellectual Property". Licensed Intellectual Property means, collectively, Licensed Technology and Licensed Patent Rights.

Section 1.42 "<u>Licensed Patent Rights</u>". Licensed Patent Rights means all Patent Rights in the Licensed Territory Controlled by MERRIMACK that claim inventions necessary or useful for the development, manufacture or Commercialization of any Licensed Product in the Licensed Territory, including MERRIMACK's rights to any Joint Patent Rights. The Licensed Patent Rights include those Patent Rights in the Licensed Territory listed on Exhibit B.

Section 1.43 "<u>Licensed Product</u>". Licensed Product means any pharmaceutical product including the Licensed Compound, or any reformulation thereof, as an active ingredient. For purposes of clarity, unless the context otherwise dictates, all references to "Licensed Product" shall include the Licensed Compound contained in such Licensed Product.

Section 1.44 "Licensed Sub-Territory.". Licensed Sub-Territory means any of the EU, Licensed Asian Territory or ROW Territory.

Section 1.45 "<u>Licensed Technology</u>". Licensed Technology means any Know-How that is Controlled (disregarding any grant of rights to BAXTER pursuant to this Agreement) by MERRIMACK, itself or jointly with BAXTER, as of the Effective Date and thereafter during the Term, that is used in, or necessary or useful for, the research, development, manufacture or Commercialization of any Licensed Product.

- Section 1.46 "Licensed Territory.". Licensed Territory means the EU, Licensed Asian Territory and ROW Territory.
- Section 1.47 "Major Asian Countries". Major Asian Countries means China, Japan, the Republic of Korea and Singapore.
- Section 1.48 "Major EU Countries". Major EU Countries means France, Germany, Italy, Spain and the United Kingdom.
- Section 1.49 "Major ROW Countries". Major ROW Countries means Argentina, Australia, Brazil, Canada, India, Mexico, Russia, South Africa, Switzerland and Turkey.
 - Section 1.50 "Manufacturing Costs". Manufacturing Costs means:
- (a) To the extent that manufacturing of any Licensed Product or any component thereof is performed by MERRIMACK or BAXTER itself, the actual consolidated, fully burdened cost incurred by MERRIMACK or BAXTER to manufacture Licensed Product or any component thereof, which costs are limited to:
 - (i) direct labor costs (salaries, wages, incentive compensation, share-based compensation and employee benefits);
 - (ii) direct materials and packaging costs;
 - (iii) operating costs of facilities and equipment, excluding any surplus or idle capacity costs;
 - (iv) a charge for depreciation, repairs and maintenance costs of facilities and equipment;
 - (v) quality and in-process control costs;
- (vi) a charge for overhead costs for raw material and manufacturing administration and management, materials management, storage and handling, and manufacturing and employee training; and
 - (vii) charges for spoilage, scrap, rework costs and expired goods;

in each of the above cases to the extent reasonably allocable to the manufacture of Licensed Product as determined in accordance with US generally accepted accounting principles, consistently applied; and/or

(b) To the extent that manufacturing of Licensed Product or any component thereof is performed for MERRIMACK or BAXTER by a Third Party, the actual amounts paid by the Party to such Third Party in connection with the manufacturing of Licensed Product or any component thereof.

- Section 1.51 "<u>Marketing Authorization</u>". Marketing Authorization means the authorization issued by the relevant Regulatory Authority necessary to place on the market a Licensed Product in any country or regulatory jurisdiction (such as, for example, the approval of a Marketing Authorization Application in EU under Regulation (EC) n° 726/2004 or Directive 2001/83/EC), including governmental price and reimbursement approvals. [**].
- Section 1.52 "<u>MERRIMACK Territory</u>". MERRIMACK Territory means all other territories outside of the Licensed Territory, including the PharmaEngine Territory.
 - Section 1.53 "MHLW". MHLW means the Japanese Ministry of Health, Labor and Welfare, and any successor agency thereto.
- Section 1.54 "MM-111". MM-111 means the MERRIMACK proprietary bispecific antibody that targets ErbB2 and ErbB3 in clinical development as of the Effective Date.
- Section 1.55 "MM-141". MM-141 means the MERRIMACK proprietary bispecific tetravalent antibody that targets IGF-1R and ErbB3 in clinical development as of the Effective Date.
- Section 1.56 "MM-302". MM-302 means the MERRIMACK proprietary HER2-targeted nanoliposomal encapsulation of doxorubicin in clinical development as of the Effective Date.
- Section 1.57 "MM-398". MM-398 means the nanoliposomal encapsulation of irinotecan described on Exhibit C, as such product may be modified after the Effective Date.
- Section 1.58 "Net Sales means the gross price invoiced by BAXTER, its Affiliates or its sublicensees in connection with the sale or other transfer for value of a Licensed Product in the Licensed Territory; less the following items (as they apply specifically to the Licensed Product) to the extent actually incurred or reasonably accrued and to the extent not separately invoiced or already deducted from the amount invoiced:
 - (a) trade, cash or quantity discounts actually allowed or taken;
- (b) governmental customs, duties, sales and similar taxes (including, for the avoidance of doubt, value added or import/export taxes, sales taxes and excise taxes but excluding taxes based on income), if any, imposed on the Licensed Product, to the extent directly related to such sale with respect to such sale;
- (c) amounts actually allowed or credited by reason of rejections, return of goods (including as a result of recalls), any retroactive price reductions or allowances specifically identifiable as relating to the Licensed Product (including those resulting from inventory management or similar agreements with wholesalers);

- (d) amounts incurred resulting from government mandated rebate programs, including programs mandated by any agency thereof;
- (e) rebates actually given to a Third Party specifically for Licensed Product;
- (f) freight, postage, shipping and applicable shipping insurance charges, to the extent same are separately itemized in the invoice price and charged to the buyer;
 - (g) patient discount programs, administrative fees and chargebacks or similar price concessions related to the sale of the Licensed Product; and
 - (h) price concessions either mandated or negotiated with commercial or governmental payers;

provided, however, that any rebate to BAXTER, gift, excess payment on other compounds or similar compensation received by BAXTER from a Third Party whether in the applicable country or any other and whether intended to be applicable to Licensed Product or not shall be added to Net Sales.

Such amounts shall be determined from the books and records of BAXTER, its Affiliates or its sublicensees, as applicable, maintained in accordance with US generally accepted accounting principles, consistently applied.

In the case of any sale of Licensed Products for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on average sales price for the applicable Licensed Product(s) in the applicable country in the entire applicable year.

Sales of Licensed Products between BAXTER and its Affiliates or its sublicensees, or among such Affiliates and sublicensees, shall be disregarded for purposes of calculating Net Sales hereunder.

In the event a Licensed Product is sold in combination with one or more other products (a "Combination Product"), Net Sales will be calculated by multiplying the Net Sales of the end user product by the fraction A over A+B, in which A is the net selling price of the Licensed Product portion of the Combination Product when such Licensed Product is sold separately during the applicable accounting period in which the sales of the Combination Product were made, and B is the net selling price of the other proprietary active ingredient(s) contained in of the Combination Product sold separately during the accounting period in question. All net selling prices of the Licensed Product portion of the Combination Product and of the other products of such Combination Product will be calculated as the average net selling price of the said ingredients during the applicable accounting period for which the Net Sales are being calculated in the particular country where the Combination Product is sold. In the event that, in any country or countries, no separate sale of either such above designated Licensed Product or such other proprietary active ingredient(s) contained in the Combination Product are made during the accounting period in which the sale was made or if the average net selling price of the other proprietary active ingredient(s) cannot be determined for an accounting period, Net Sales allocable to the Licensed Product in each such country will be determined by mutual agreement reached in good faith by BAXTER and MERRIMACK prior to the end of the accounting period in question.

Section 1.59 "Other Indication". Other Indication means any use of the Licensed Compound or any Licensed Product in a cancer indication other than the First Indication or the Second Indication.

- Section 1.60 "Party". Party means BAXTER or MERRIMACK; "Parties" means BAXTER and MERRIMACK.
- Section 1.61 "Patent Right". Patent Right means (a) unexpired and currently in-force letters patent (or other equivalent legal instrument), including utility and design patents, and including any extension, substitution, registration, confirmation, reissue or renewal thereof, (b) applications for letters patent, a reissue application, a continuation application, a continuation-in-part application, a divisional application or any equivalent of the foregoing applications, that are pending at any time during the term of this Agreement before a government patent authority and (c) all foreign or international equivalents of any of the foregoing in any country.
- Section 1.62 "<u>Person</u>". Person means any natural person or any corporation, company, partnership, limited liability company, joint venture, firm, agency or other entity, including a Party.
- Section 1.63 "<u>PharmaEngine</u>". PharmaEngine means PharmaEngine, Inc., a company organized and existing under the laws of the Republic of China with its principal offices at 16F, 237, Sung-Chiang Road, Taipei, Taiwan 104, Republic of China.
- Section 1.64 "<u>PharmaEngine Collaboration Agreement</u>". PharmaEngine Collaboration Agreement means the Assignment, Sublicense and Collaboration Agreement, dated May 5, 2011, by and between MERRIMACK (as successor-in-interest to Merrimack Pharmaceuticals (Bermuda) Ltd.) and PharmaEngine.
 - Section 1.65 "PharmaEngine Territory". PharmaEngine Territory means Taiwan.
- Section 1.66 "<u>Phase 3 Clinical Study</u>". Phase 3 Clinical Study means a controlled study in humans of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to file a Drug Approval Application to obtain Marketing Authorization, as further defined in 21 C.F.R. Part 312.21(c) (or the non-US equivalent thereof).
- Section 1.67 "<u>Pivotal Clinical Study</u>". Pivotal Clinical Study shall mean a human clinical study, including any Phase 3 Clinical Study, the results of which, if the pre-defined endpoints are met, are intended to provide data necessary to support Marketing Authorization for the Licensed Product in any country.
- Section 1.68 "Regulatory Approval". Regulatory Approval means any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary for the manufacture, use, storage, import, promotion, marketing and sale of a product in a country or jurisdiction, including Marketing Authorizations.

Section 1.69 "Regulatory Authority". Regulatory Authority means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the testing, approval, manufacture, use, storage, import, promotion, marketing or sale of a product in a country, including the FDA, EMA or MHLW.

Section 1.70 "Regulatory Exclusivity.". Regulatory Exclusivity means any rights or protections which are recognized, afforded or granted by any Regulatory Authority in any country or region of the Licensed Territory in association with obtaining Marketing Authorization for the Licensed Product, providing such Licensed Product: (a) a period of marketing exclusivity during which the applicable Regulatory Authority shall refrain from either reviewing or approving a Marketing Authorization application or similar regulatory submission submitted by a Third Party seeking to market a competing product, or (b) a period of data exclusivity during which a Third Party seeking to market a competing product and/or the Regulatory Authority responsible for granting Marketing Authorization therefor is precluded from either referencing or relying upon, without an express right of reference from the dossier holder, such Licensed Product's clinical dossier or relying on previous Regulatory Authority findings of safety or effectiveness with respect to such Licensed Product to support the submission, review or approval of a Marketing Authorization application or similar regulatory submission before the applicable Regulatory Authority. Regulatory Exclusivity shall include rights conferred in the EU pursuant to Section 10.1(a)(iii) of Directive 2001/EC/83.

Section 1.71 "Regulatory Filings". Regulatory Filings means any Drug Approval Application, notification or other submission made to or with a Regulatory Authority that is necessary or reasonably desirable to develop, manufacture or Commercialize the Licensed Product in the Licensed Field in a particular country or regulatory jurisdiction, whether made before or after receipt of Marketing Authorization in the country or regulatory jurisdiction, and any approval resulting from any such application is a "Regulatory Approval". The term "Regulatory Filings" shall include all amendments and supplements to any of the foregoing and all proposed labels, labeling, package inserts, monographs and packaging for a Licensed Product in a particular country.

Section 1.72 "ROW Territory". ROW Territory means all countries of the world, excluding the US, EU, Licensed Asian Territory and Taiwan.

Section 1.73 "<u>Second Indication</u>". Second Indication means the treatment of advanced, locally-advanced or metastatic pancreatic cancer patients who (a) have not received previous treatment with a gemcitabine-containing regimen or (b) [**].

Section 1.74 "Taiwan". Taiwan means the Republic of China.

Section 1.75 "Third Party". Third Party means any Person other than a Party or any of its Affiliates.

Section 1.76 "US". US means the United States of America, its territories and possessions.

Section 1.77 "Valid Claim". Valid Claim means (a) a claim of an issued patent that has not expired or been abandoned, or been revoked, held invalid or unenforceable by a patent office, court or other governmental agency of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period); or (b) a claim of a pending patent application which claim has not been revoked, cancelled, withdrawn or abandoned and that has not been pending for more than [**] years from the date such claim, or a claim of substantially identical scope, was first presented in any patent application in the same country.

Section 1.78 Additional Definitions. Each of the following definitions is set forth in the section of this Agreement indicated below:

Definitions Exhibit E 1934 Act 1974 Convention Section 15.1 Additional Response Period Section 6.2(b) Agreement Preamble Alliance Manager Section 2.1(c) **Arbitration Request** Section 13.2(a) Preamble **BAXTER** Section 3.7 **BAXTER Supply Agreement** Preamble BHC **BHSA** Preamble Preamble BII **Biological Materials** Section 3.4(e) **Breaching Party** Section 12.3 Claims Section 14.1 Competitive Infringement Section 9.3(a) Confidentiality Agreement Section 1.14 CPI Section 1.30 **CPR** Section 13.2(d) **CPR Rules** Section 13.2(d) [**] FTE Rate Section 1.30 Preamble Effective Date Section 9.2(e)(iii) EPO Flow-Through Sections Section 7.4(a) Section 4.1(b) Global Dossier **Indemnified Party** Section 14.3(a) **Indemnifying Party** Section 14.3(a) Initial Global Development Plan Section 1.31 Initial Press Release Section 10.3 Invalidity Claim Section 9.5(a) Joint Inventions Section 9.1(b) JSC Section 2.1(a) Licensing Opportunity Section 6.2(a) Losses Section 14.1 Manufacturing Technology Section 3.8(a)(i)

Definitions Location MERRIMACK Preamble MERRIMACK Supply Agreement Section 3.6 Negotiation Period Section 6.2(c) New Baxter Section 15.2 NDA Section 1.18 Non-Breaching Party Section 12.3 Patent Challenge Section 12.5 Patent Prosecution Section 9.2(e) **Paying Party** Section 8.11(a) **PCT** Section 9.2(a) **Publishing Party** Section 10.5(a) Quality Section 3.9 Section 3.9 Quality Agreement **Recipient Party** Section 8.11(a) Response Period Section 6.2(a) Section 6.2 ROFN Program(s) Royalty Term Section 8.5(b) **SDEA** Section 4.4 SEC Section 10.1(e) Severed Clause Section 15.14 [**] FTE Rate Section 1.30 Section 12.1 Term **Terminated Products** Section 12.7 **Terminated Territories** Section 12.7 Third Party License Section 8.5(c)(i) Third Party License Costs Section 8.5(c)(i) USPTO Section 9.2(e)(iii) WIPO Section 9.2(e)(iii) Withholding Taxes Section 8.11(a)

Article II <u>Governance; Decision-Making</u>

Section 2.1 Joint Steering Committee.

(a) <u>Formation and Membership</u>. Within [**] days after the Effective Date, BAXTER and MERRIMACK shall establish a joint steering committee (the "<u>JSC</u>") to review, coordinate and provide overall strategic direction to their activities pursuant to this Agreement. The JSC shall be comprised of [**] senior executives of BAXTER and [**] senior executives of MERRIMACK with appropriate experience and level of decision-making authority. Each Party may replace any one or more of its representatives on the JSC at any time upon written notice to the other Party. From time-to-time, the JSC may, in its discretion, establish one or more subcommittees or project teams to oversee particular projects or activities, as the JSC deems necessary or advisable and the JSC may, in its discretion, establish one or more project teams, to, upon mutual agreement of the Parties, implement and coordinate various aspects of the Global Development Plan and Global Marketing and Commercialization Principles.

(b) <u>Responsibilities</u>. The JSC shall be responsible for and shall have final decision-making authority with respect to the following matters related to the development and Commercialization of the Licensed Compound and all Licensed Products:

- (i) approving changes to the Initial Global Development Plan and initial budget;
- (ii) annually (or more frequently as agreed by the JSC) reviewing the Global Development Plan and suggesting or approving such updates or amendments to the Global Development Plan, as the JSC deems appropriate, including all budget amendments;
- (iii) providing overall strategic direction with respect to development and regulatory activities conducted under the Global Development Plan;
- (iv) overseeing the research and development of the Licensed Compound and any Licensed Product in accordance with the Global Development Plan;
- (v) overseeing the progress of development activities relating to the Global Development Plan and monitoring the Parties' compliance with their respective obligations under the Global Development Plan, including the accomplishment of key objectives;
 - (vi) overseeing the development of the Global Marketing and Commercialization Principles;
 - (vii) approving the Global Marketing and Commercialization Principles;
 - (viii) reviewing all changes, updates and amendments to the Global Marketing and Commercialization Principles;
- (ix) periodically reviewing the Global Marketing and Commercialization Principles and suggesting or approving such updates or amendments to the Global Marketing and Commercialization Principles, as the JSC deems appropriate;
- (x) overseeing the formation and operation of any subcommittees or project teams and the Parties' progress in the conduct of activities under the Global Development Plan and Global Marketing and Commercialization Principles hereunder;
 - (xi) reviewing and approving the protocols of all clinical studies;
- (xii) discussing, reviewing and approving a joint publication strategy with respect to the publication of results of any clinical trial conducted by the Parties with respect to the Licensed Compound and any Licensed Product;
 - (xiii) discussing, reviewing and approving an investigator initiated trial strategy and related budget;

(xiv) providing strategic direction with respect to development activities for the Licensed Compound and any Licensed Product;

(xv) discuss, review and approve any issues related to the development or commercialization of a Companion Diagnostic in the Licensed Territory, provided that each Party shall have the obligation to notify the JSC of any potential Companion Diagnostic that such Party acquires, in-licenses or has developed or intends to acquire, in-license or develop, and, at the request of the other Party following any such notification, the Parties shall discuss in good faith terms and conditions (including financial terms) under which the notifying Party would grant the other Party access or rights to such potential Companion Diagnostic to the extent Controlled by the notifying Party;

(xvi) attempting to resolve disputes arising under this Agreement at the JSC, any subcommittees or project teams of either of the Parties (for clarity, the JSC shall not have the authority to resolve disputes between the Parties regarding whether a Party has fulfilled or breached any obligation under this Agreement);

(xvii) subject to the terms of the MERRIMACK Supply Agreement and the BAXTER Supply Agreement, if applicable, overseeing and providing strategic direction to the manufacture of the Licensed Product for the Licensed Territory, including discussing, preparing and approving a manufacturing plan for each Licensed Product for the Licensed Territory and overseeing implementation of each such manufacturing plan; and

(xviii) performing such other tasks and undertaking such other responsibilities as may be set forth in this Agreement.

- (c) <u>Alliance Managers</u>. Each Party shall appoint one representative to serve as an alliance manager ("<u>Alliance Manager</u>") with responsibility for overseeing that the Parties' activities are conducted in accordance with this Agreement, and for being the primary point of contact between the Parties with respect to all such activities. The Alliance Manager is responsible for driving the alliance progress and the resolution of issues between the Parties.
- (d) <u>Administrative Matters</u>. The JSC shall have a chairperson who shall serve for a term of one (1) year from the date of appointment. MERRIMACK and BAXTER shall alternate the appointment of the JSC chairperson, with the initial JSC chairperson appointed by [**]. The chairperson shall work together with the Alliance Managers to develop the JSC meeting agendas, which shall be circulated to all JSC members at least [**] Business Days in advance of the meetings. The chairperson shall be responsible for calling meetings of the JSC and for leading the meetings. A JSC member from the Party that has not appointed the chairperson shall serve as secretary of such meetings (or shall appoint a secretary who does not need to be a JSC member). The secretary shall prepare and distribute to all members of the JSC draft minutes of the meeting for review and comment, including a list of any actions or decisions approved by the JSC, with the goal of distributing final approved minutes of each JSC meeting within [***] days after the meeting.
- (e) <u>Decision-Making</u>. Each Party shall have one (1) vote on the JSC. The JSC shall operate by consensus and both Parties must vote in the affirmative to allow the JSC to

take any action that requires the approval of the JSC. Decisions on any matter may be taken at a meeting, by teleconference, videoconference or by written agreement. Either Party may convene a special meeting of the JSC in accordance with Section 2.1(g)(iii) for the purpose of resolving any disagreement within the JSC's jurisdiction in case any such disagreement represents a material issue, the resolution of which cannot reasonably wait until the next scheduled meeting of the JSC. Subject to Section 2.1(f), the following decisions shall not be made by the JSC but shall be made in good faith exclusively by MERRIMACK or BAXTER, as the case may be:

- (i) [**] shall have final decision-making authority with respect to matters relating to the conduct of [**] Territory-specific clinical trials and other [**] Territory-specific development activities unless [**] objects to a proposed [**] Territory-specific clinical trial or [**] Territory-specific development activity based on bona fide scientific, technical or safety concerns that could affect the Licensed Product in the [**] Territory;
- (ii) [**] shall have final decision-making authority with respect to matters relating to the conduct of [**] Territory-specific clinical trials and other [**] Territory-specific development activities unless [**] objects to a proposed [**] Territory-specific clinical trial or other [**] Territory-specific development activity based on bona fide scientific, technical or safety concerns that could affect the Licensed Product in the [**] Territory;
- (iii) [**] shall have final decision-making authority with respect to Commercialization in the [**] Territory, subject to [**] material compliance with the Global Marketing and Commercialization Principles;
- (iv) [**] shall have final decision-making authority with respect to Commercialization in the [**] Territory, subject to [**] material compliance with the Global Marketing and Commercialization Principles; and
- (v) [**] shall have final decision-making authority with respect to the development and Commercialization of a Companion Diagnostic in the [**] Territory, subject to any subsequent agreement into which the Parties might enter regarding such development and Commercialization.

For the avoidance of doubt, neither the JSC nor either Party shall have final decision-making authority over interpretations of, amendments to or disputes regarding the Parties' respective rights and obligations under this Agreement.

(f) <u>Dispute Resolution by Executive Officers</u>. If (i) the JSC is unable to reach consensus on a particular issue or resolve any dispute within the responsibilities of the JSC specified in Section 2.1(b) within [**] days after such issue or dispute is first presented to the JSC, or (ii) either Party objects to a territory-specific clinical trial or development activity proposed to be taken by the other Party pursuant to Section 2.1(e)(i) or Section 2.1(e)(ii), then such issue shall be resolved pursuant to the dispute resolution processes set forth in Article XIII.

(g) Meetings.

(i) The JSC shall meet at least [**] and at least [**] meetings each year shall be in-person, alternating between the Parties' respective locations in the US (or a

location outside of the US that is mutually agreed to by the Parties). The specific timing and location of JSC meetings shall be as determined by the chairperson, and may be held in person, by telephone conference call or by videoconference.

- (ii) Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the JSC. In addition, each Party may, with the prior consent of the chairperson, invite a reasonable number of non-voting employees or officers, consultants or scientific advisors, to attend meetings of the JSC or the relevant portion thereof, provided that any such consultants or scientific advisors are bound by written obligations of confidentiality that are at least as stringent as those set forth in this Agreement. Notwithstanding the foregoing, neither Party's legal counsel may attend a JSC meeting without sufficient prior notice to the other Party to allow that other Party's counsel to attend or to expressly waive attendance.
- (iii) Each Party may also call a special meeting of the JSC for the purpose of resolving disputes in connection with, or for the purpose of reviewing or making a decision pertaining to, any material matter within the purview of the JSC, the examination or resolution of which cannot reasonably be postponed until the next scheduled JSC meeting, by providing written notice to the other Party. Such meeting shall be convened at such time as may be mutually agreed upon by the Parties, but in any event shall be held within [**] days after the date of such notice.

Article III <u>Development; Manufacture and Supply</u>

Section 3.1 Overview; Global Development Plan.

- (a) Subject to and in accordance with the terms and conditions of this Agreement, including Section 3.4, the Parties shall collaborate on the research and development of the Licensed Compound and Licensed Product(s) in accordance with the Global Development Plan. Unless otherwise agreed by the Parties or decided by the JSC, MERRIMACK shall be responsible for conducting and shall be the "sponsor" of all clinical trials contemplated by the Global Development Plan. The Global Development Plan, and any change, update or amendment to the Global Development Plan, shall be prepared by MERRIMACK in consultation with BAXTER, shall be reviewed and approved by the JSC, shall be consistent with the terms and conditions of this Agreement and shall specify, among other things:
 - (i) research and development objectives;
- (ii) activities to be performed, including all clinical trials and Regulatory Approvals required for manufacturing, marketing and selling Licensed Products;
 - (iii) timelines for performance; and
 - (iv) specific deliverables.
- (b) Each Party shall use Commercially Reasonable Efforts to perform its respective obligations under the Global Development Plan in accordance with the Global Development Plan and all applicable Laws.

Section 3.2 Second Indication Development Costs.

- (a) <u>Development Costs Prior to Effective Date</u>. MERRIMACK shall, except as otherwise provided in this Agreement as to inventory of Licensed Product and Comparator Drug existing as of the Effective Date, be responsible for and shall pay all Development Costs incurred prior to the Effective Date.
- (b) Second Indication Development Costs. MERRIMACK shall pay for all Development Costs incurred by it in performing activities under the Initial Global Development Plan necessary to obtain initial Marketing Authorizations for the Second Indication; provided, however, if Development Costs for activities for the Second Indication under the Initial Global Development Plan exceed the budget for the Second Indication set forth in the Initial Global Development Plan, then (i) Development Costs in excess of the budget for the Second Indication set forth in the Initial Global Development Plan shall be shared equally between BAXTER and MERRIMACK and (ii) BAXTER shall pay to MERRIMACK BAXTER's share of such Development Costs incurred by MERRIMACK, within [**] days following MERRIMACK's invoice therefor.
- (c) <u>Additional Development Costs</u>. If the JSC determines that an additional clinical trial or other development activity for the Second Indication that is not contemplated by the Initial Global Development Plan is required or advisable for the Commercialization of the Licensed Compound or Licensed Product, then the Development Costs for such additional clinical trial or other development activity other than Development Costs exclusively related to either the Licensed Territory or the MERRIMACK Territory (and paid directly by either BAXTER or MERRIMACK pursuant to Section 3.4) will be shared equally between BAXTER and MERRIMACK. BAXTER shall pay to MERRIMACK BAXTER's share of such Development Costs incurred by MERRIMACK, within [**] days following MERRIMACK's invoice therefor, and MERRIMACK shall pay to BAXTER MERRIMACK's share of such Development Costs incurred by BAXTER, within [**] days following BAXTER's invoice therefor.
- Section 3.3 Other Development Costs. Development Costs incurred pursuant to the Global Development Plan other than Development Costs allocated pursuant to Section 3.2 and other than Development Costs exclusively related to either the Licensed Territory or the MERRIMACK Territory (and paid directly by either BAXTER or MERRIMACK pursuant to Section 3.4) shall be shared equally between BAXTER and MERRIMACK. BAXTER shall pay to MERRIMACK BAXTER's share of such Development Costs incurred by MERRIMACK, within [**] days following MERRIMACK's invoice therefor, and MERRIMACK shall pay to BAXTER MERRIMACK's share of such Development Costs incurred by BAXTER, within [**] days following BAXTER's invoice therefor.

Section 3.4 Certain Development Responsibilities of Each Party.

(a) As to the Licensed Compound and Licensed Product(s) in each indication, BAXTER shall (i) be solely responsible, at BAXTER's sole expense, for conducting all clinical trials (for which BAXTER shall be the "sponsor") and other development activities that exceed those clinical trials and development activities that are set forth in the Global Development Plan

that are solely required to obtain Regulatory Approval to manufacture, market and sell the Licensed Compound or Licensed Product(s) specifically for the Licensed Territory and (ii) be solely responsible for all costs of modifications to global clinical trials and other development activities made solely to obtain Regulatory Approval to manufacture, market and sell the Licensed Compound or Licensed Product(s) for the Licensed Territory.

- (b) As to the Licensed Compound and Licensed Product(s) in each indication, MERRIMACK shall (i) be solely responsible, at MERRIMACK's sole expense, for conducting all clinical trials (for which MERRIMACK shall be the "sponsor") and other development activities that exceed those clinical trials and development activities that are set forth in the Global Development Plan that are solely required to obtain Regulatory Approval to manufacture, market and sell the Licensed Compound or Licensed Product(s) specifically for the MERRIMACK Territory and (ii) be solely responsible for all costs of modifications to global clinical trials and other development activities made solely to obtain Regulatory Approval to manufacture, market and sell the Licensed Compound or Licensed Product(s) for the MERRIMACK Territory.
- (c) If either Party intends to conduct a clinical trial or other development activity pursuant to this Section 3.4 that is not contemplated by the Global Development Plan and that is necessary to obtain Regulatory Approval in the Licensed Territory, such Party shall inform and provide no less than [**] days' prior written notice to the JSC of such intended clinical trial or development activity and will reasonably consider any input of the JSC on such clinical trial.
- (d) As further set forth in Article IV and except as otherwise provided in Section 4.1(c)(i) and Section 4.1(h), (i) BAXTER shall be responsible for preparing, filing, obtaining and maintaining all Regulatory Approvals necessary to develop, manufacture, market and sell the Licensed Compound and Licensed Product(s) in the Licensed Territory and (ii) MERRIMACK shall be responsible for preparing, filing, obtaining and maintaining all Regulatory Approvals necessary to develop, manufacture, market and sell the Licensed Compound and Licensed Product(s) in the MERRIMACK Territory.
- (e) For purposes of facilitating the conduct of the Global Development Plan, each Party shall provide to the other Party animal or human tissues, cells, blood samples and other materials ("<u>Biological Materials</u>") specified from time to time in the Global Development Plan and applicable Laws. Each Party agrees to provide all such Biological Materials to the other Party in accordance with the Global Development Plan. The Parties agree that:
- (i) all Biological Materials provided by one Party to the other shall be used by the receiving Party solely for research and development purposes for the Licensed Compound or any Licensed Product in material compliance with all applicable Laws;
 - (ii) all such Biological Materials are provided without any warranties, express or implied;

(iii) the Party providing such Biological Materials shall obtain (or cause its Third Party collaborators to obtain or certify that they have obtained) all appropriate and required consents from the source of such Biological Materials; and

(iv) Biological Materials provided by one Party to the other shall not be made available by the other Party to any Third Party except as contemplated in the Global Development Plan or upon the prior written consent of the Party providing such Biological Materials.

Section 3.5 Clinical Supply.

- (a) MERRIMACK shall manufacture and supply (or have manufactured or supplied) clinical supplies of Licensed Product for use by the Parties in the development of Licensed Product on a delivery schedule and other customary supply terms and conditions as are mutually agreed by the Parties.
- (b) Within [**] days following MERRIMACK's invoice therefor, BAXTER shall pay MERRIMACK for [**] percent ([**]%) of all Manufacturing Costs for clinical supply of Licensed Product and Comparator Drug for Global Development Plan activities incurred by MERRIMACK (excluding, for clarity, costs associated with clinical supply of Licensed Product and Comparator Drug for development activities conducted pursuant to Section 3.2(a), Section 3.4(a) and Section 3.4(b), which shall be borne solely by the applicable Party). Notwithstanding Section 3.2(a), such Manufacturing Costs may include such costs incurred prior to the Effective Date by MERRIMACK for clinical supply of the Licensed Product used for Global Development Plan activities after the Effective Date.

Section 3.6 <u>MERRIMACK Supply Agreement</u>. On or before a date to be established by the JSC, but in no event later than [**] days after the Effective Date, MERRIMACK shall use Commercially Reasonable Efforts and shall cooperate with BAXTER to become an approved BAXTER supplier and the Parties shall enter into a supply agreement (the "<u>MERRIMACK Supply Agreement</u>") pursuant to which MERRIMACK will supply Drug Product to BAXTER. The terms of such MERRIMACK Supply Agreement shall be negotiated in good faith by the Parties and will contain customary terms and conditions that are consistent with this Agreement and the agreed-upon terms attached hereto as <u>Exhibit D</u>.

Section 3.7 <u>Secondary Supply</u>. Within [**] days after the Effective Date, BAXTER shall elect, and notify MERRIMACK of such election, either (a) to commit to establishing commercial scale manufacturing capabilities for Drug Product either directly or through a Third Party and, if BAXTER elects, Licensed Product, or (b) not to commit to establishing such capabilities. If BAXTER makes the election set forth in the foregoing clause (a), BAXTER shall thereafter use Commercially Reasonable Efforts to establish such capabilities at BAXTER's sole expense and BAXTER and MERRIMACK shall enter into a supply agreement (the "<u>BAXTER Supply Agreement</u>") pursuant to which BAXTER will supply Drug Product to MERRIMACK. The terms of such BAXTER Supply Agreement shall be negotiated in good faith by the Parties and will contain customary terms and conditions that are consistent with this Agreement and the agreed-upon terms attached hereto as <u>Exhibit D</u>. If BAXTER makes the election set forth in the foregoing clause (b), MERRIMACK will develop a plan for the construction of a facility to serve

as a second Drug Product manufacturing facility, including a budget therefor. MERRIMACK will review such plan with the JSC (or appropriate working group of the JSC). MERRIMACK will have no obligation to pursue any such plan unless and until MERRIMACK secures financing for such plan that is satisfactory to MERRIMACK in its discretion, which financing may include BAXTER providing MERRIMACK with a line of credit, and such plan is otherwise satisfactory to MERRIMACK in its discretion.

Section 3.8 <u>Technology Transfer</u>. If BAXTER elects option (a) pursuant to Section 3.7, or at any time thereafter if BAXTER determines to establish its own commercial scale manufacturing, then MERRIMACK shall perform a technology transfer of MERRIMACK's manufacturing process for the Drug Product and/or Licensed Product to BAXTER (or its designated Affiliate or CMO), which technology transfer shall be performed in accordance with a mutually agreed technology transfer plan, timeline and budget.

- (a) As part of such technology transfer to BAXTER (or BAXTER's designated Affiliate or CMO), MERRIMACK shall:
- (i) subject to BAXTER's prior approval of a budget, transfer to BAXTER (or BAXTER's designated Affiliate or CMO) copies of Regulatory Filings and other Licensed Technology that are necessary or useful for BAXTER (or the Affiliate or CMO identified by BAXTER) to manufacture the Drug Product and/or Licensed Product, including manufacturing processes, analytical methods, specifications, protocols, assays, batch records, quality control data, transportation and storage requirements, and other manufacturing documentation or files (collectively, "Manufacturing Technology"); and
- (ii) provide technical assistance to BAXTER (or BAXTER's Affiliate or designated CMO) with respect to the use and implementation of such Manufacturing Technology as may be mutually agreed by the Parties.
- (b) BAXTER shall pay MERRIMACK, within [**] days following MERRIMACK's invoice, for (i) all internal costs of MERRIMACK personnel at the [**] FTE Rate, plus (ii) all out-of-pocket costs and expenses incurred by MERRIMACK, to the extent incurred in performing the technology transfer activities contemplated hereunder, and provided that all aforesaid costs and expenses do not exceed the amounts set forth in the corresponding budget set forth in the agreed technology transfer plan, it being understood that such approved budget shall incorporate into the budget an allowance of [**] percent ([**]%) for cost overruns, provided that such overruns, upon their occurrence, are appropriately documented and justified.
- (c) The Parties will cooperate in good faith in undertaking all such technology transfer activities, including with respect to the scheduling and planning of associated meetings.

Section 3.9 <u>Quality Agreement</u>. In connection with the negotiation and execution of the MERRIMACK Supply Agreement or the BAXTER Supply Agreement, as applicable, the Parties shall also enter into a separate agreement governing the quality control, quality assurance and validation (the "<u>Quality</u>") of any Drug Product and/or Licensed Product (as applicable) delivered to BAXTER under the MERRIMACK Supply Agreement or delivered to MERRIMACK under the BAXTER Supply Agreement (each a "<u>Quality Agreement</u>"). Any

Quality Agreement shall be negotiated in good faith by the Parties, will contain customary terms and conditions that are consistent with this Agreement, and shall set forth the respective requirements, roles and responsibilities of the Parties.

Section 3.10 <u>Development Reports</u>. Each Party shall provide written reports to the other Party within [**] days after the end of each [**] month period (i.e., [**]) during each calendar year during the Term, setting forth in reasonable detail such Party's and its Affiliates' and sublicensees' (a) activities and progress during such preceding [**] month period related to the pre-commercial research, development and manufacture of the Licensed Compound and Licensed Product(s), including [**].

Article IV Regulatory Matters

Section 4.1 Overview; Regulatory Filings.

- (a) BAXTER will prepare the Drug Approval Applications for the Licensed Territory and thereafter will maintain such Drug Approval Applications and resulting Marketing Authorizations. MERRIMACK will, if requested by BAXTER, assist BAXTER in preparing responses to any EMA inquiries during the review cycle for the First Indication until receipt of Marketing Authorization in the Licensed Territory.
- (b) BAXTER will be responsible (in collaboration with MERRIMACK through the JSC) for the creation and control of a global dossier (the "Global Dossier") using Electronic BAXTER Data Management Standards, which BAXTER shall use as the basis for all Drug Approval Applications and Regulatory Filings in the Licensed Territory, provided that the creation of such Global Dossier shall not be required to be pursued in any manner that results in delays in the development of the Licensed Product in the MERRIMACK Territory. The Parties agree to create such Global Dossier at BAXTER's sole expense.
 - (c) Within [**] days following the Effective Date, MERRIMACK shall:
- (i) transfer to BAXTER ownership of all Drug Approval Applications, Regulatory Approvals and Regulatory Filings submitted to any Regulatory Authority for the Licensed Compound and any Licensed Products that are in MERRIMACK's name and Controlled by MERRIMACK in the Licensed Territory, provided that MERRIMACK shall not transfer to BAXTER any IND relating to clinical studies of the Licensed Compound or Licensed Product conducted by or on behalf of MERRIMACK; or
- (ii) to the extent that such transfer is not permitted under applicable Laws, provide to BAXTER a right of reference or use to such Regulatory Approvals and Regulatory Filings.
- (d) MERRIMACK shall retain all Regulatory Approvals and Regulatory Filings submitted to any Regulatory Authority for the Licensed Compound and any Licensed Product that are in MERRIMACK's name and Controlled by MERRIMACK in the MERRIMACK Territory.

(e) Subject to Section 4.1(c)(i) and Section 4.1(h), following the Effective Date, BAXTER shall own and be responsible for preparing, filing and maintaining all Regulatory Filings and Regulatory Approvals that are required for the research, development, manufacture, use, marketing or sale of the Licensed Compound and Licensed Product in the Licensed Territory, provided that:

- (i) MERRIMACK shall provide BAXTER with assistance as may be reasonably requested by BAXTER for the maintenance of the Global Dossier;
- (ii) MERRIMACK shall have a right of reference or use to such Regulatory Filings and Regulatory Approvals to the extent necessary for the conduct of MERRIMACK's activities with respect to the Licensed Product in the MERRIMACK Territory (and MERRIMACK shall have the right to extend such right of reference or use to PharmaEngine);
- (iii) BAXTER shall provide MERRIMACK with copies of material regulatory submissions to, and material communications with, Regulatory Authorities in the Licensed Territories and MERRIMACK shall have the right to review and comment on such submissions and communications, in each case as set forth in Section 4.2(a) below; and
- (iv) BAXTER shall take such actions and otherwise cooperate with MERRIMACK as may be reasonably requested by MERRIMACK to enable MERRIMACK to conduct the clinical trials and perform other development, regulatory and manufacturing activities assigned to MERRIMACK under the Global Development Plan.
- (f) Each Party will cooperate with the other Party with respect to any required correspondence with Regulatory Authorities required to transfer ownership of any Regulatory Filings pursuant to this Section 4.1.
- (g) BAXTER shall pay MERRIMACK, within [**] days following MERRIMACK's monthly invoice, [**] expenses incurred by MERRIMACK pursuant to this Section 4.1, including (i) [**] at the [**] FTE Rate, plus (ii) [**] incurred by MERRIMACK, with respect to each of clause (i) and (ii) to the extent incurred in transferring to BAXTER Regulatory Approvals and Regulatory Filings (or providing BAXTER with a right of reference thereto) and providing regulatory assistance to BAXTER.
- (h) Following the Effective Date, MERRIMACK shall own and be responsible for preparing, filing and maintaining all Regulatory Filings and Regulatory Approvals that are required for the research, development, manufacture, use, marketing or sale of the Licensed Compound and Licensed Product in the MERRIMACK Territory, as well as any IND relating to clinical studies of the Licensed Compound or Licensed Product conducted by or on behalf of MERRIMACK, provided that:
- (i) BAXTER shall provide MERRIMACK with assistance as may be reasonably requested by MERRIMACK with respect to Regulatory Filings in accordance with the Global Development Plan in the MERRIMACK Territory for which BAXTER shall be reimbursed based on the [**] FTE Rate and all reasonably incurred expenses;

(ii) BAXTER shall have a right of reference and right to use such Regulatory Filings and Regulatory Approvals to the extent necessary for the conduct of BAXTER's activities under this Agreement, in the Licensed Territory;

- (iii) MERRIMACK shall provide BAXTER with copies of all regulatory submissions to, and material communications with, Regulatory Authorities in the Licensed Territories and BAXTER shall have the right to review and comment on such submissions and communications as to the Licensed Territory, in each case as set forth in Section 4.2(a) below; and
- (iv) MERRIMACK shall take such actions and otherwise cooperate with BAXTER as may be reasonably requested by BAXTER to enable BAXTER to conduct the clinical trials and perform other development, regulatory and manufacturing activities assigned to BAXTER under the Global Development Plan; provided, however, that MERRIMACK shall serve as the "sponsor" for all clinical trials contemplated by the Global Development Plan.

Section 4.2 Communications with Regulatory Authorities.

- (a) Following the Effective Date, subject to Section 4.1(c)(i) and Section 4.1(h), BAXTER shall be responsible for all submissions to, and communications and interactions with, Regulatory Authorities in the Licensed Territory with respect to the Licensed Compound and Licensed Product, provided that:
- (i) BAXTER shall keep MERRIMACK promptly informed regarding BAXTER's (or its Affiliate's or sublicensee's) regulatory strategy, planned regulatory submissions and material communications with Regulatory Authorities in the Licensed Territories with respect to the Licensed Compound and all Licensed Products, including any changes to such strategy, submissions or communications;
- (ii) BAXTER shall provide MERRIMACK with copies, for information, of material regulatory submissions to, and material communications with, any Regulatory Authorities in the Licensed Territories relating to the Licensed Compound and Licensed Products and MERRIMACK shall have an opportunity to review in advance and comment on all such planned regulatory submissions; and
- (iii) BAXTER shall give due consideration in good faith to incorporating any and all comments provided by MERRIMACK on any planned regulatory submissions to, or material communications with, any Regulatory Authorities in the Licensed Territory with respect to such clinical trial (or the results thereof) or the Licensed Compound or Licensed Product used in such clinical trial, unless such comments are unreasonable.
- (b) Following the Effective Date, MERRIMACK shall be responsible for all submissions to, and communications and interactions with, Regulatory Authorities in the MERRIMACK Territory with respect to the Licensed Compound and Licensed Product, provided that as to any human clinical trial for the Licensed Compound or Licensed Product for a given indication conducted or to be conducted under the Global Development Plan, MERRIMACK shall give due consideration in good faith to incorporating any and all comments provided by BAXTER on any planned regulatory submissions to, or material communications with, any Regulatory Authorities in the MERRIMACK Territory with respect to such clinical trial, unless such comments are unreasonable.

(c) In addition to each Party's rights and obligations under clauses (a) and (b), each Party shall provide the other Party, if feasible, with reasonable advance notice of any material meeting or substantive telephone conference with any regulatory agency in the Licensed Territory or MERRIMACK Territory (including the FDA, MHLW or EMA) relating to the Licensed Compound or Licensed Product(s).

(d) Without limiting the generality of any of the foregoing in this Section 4.2(d), each Party shall also promptly provide the other Party with a copy of all material correspondence that such Party (or its Affiliate or sublicensee) receives from, or submits to, any Regulatory Authorities in the Licensed Territory or MERRIMACK Territory, as applicable, including contact reports concerning conversations or substantive meetings, contact reports of all Regulatory Authority interactions concerning conversations or substantive meetings, all IND annual reports (including any equivalent filings outside the US), manufacturing-related regulatory submissions and correspondence, development safety update reports and cover letters of all agency submissions (it being understood that either Party may request, and shall then receive, copies of all attachments to any such cover letters) relating to the Licensed Compound or Licensed Product(s), each to the extent material. Each Party shall also provide the other Party with any meeting minutes that such Party prepares that reflect material communications with any Regulatory Authorities in the Licensed Territory or MERRIMACK Territory, as applicable, regarding the Licensed Compound or Licensed Product(s).

(e) The Parties will cooperate in providing technical regulatory expertise for assistance in developing the submission strategy for Regulatory Filings and defining technical content in the Licensed Territory. Each Party shall designate a global regulatory affairs representative to represent it in connection with such Regulatory Filings. Each such representative or such representative's designee along with other subject matter experts (as needed) will be invited to attend critical meetings with Regulatory Authorities associated with the submission of Regulatory Filings for Licensed Products in the Licensed Territory.

Section 4.3 <u>Product Withdrawals and Recalls</u>. If any Regulatory Authority (a) threatens, initiates or advises any action to remove any Licensed Product from the market in either the Licensed Territory or the MERRIMACK Territory, or (b) requires or advises either Party or such Party's Affiliates or sublicensees to distribute a "Dear Doctor" letter or its equivalent regarding use of such Licensed Product, then the Party receiving notice from the Regulatory Authority shall notify the other Party of such event within [**] Business Days (or sooner if required by applicable Laws) after such Party becomes aware of the action, threat, advice or requirement. The JSC will discuss and attempt to agree upon whether to recall or withdraw a Licensed Product in the Licensed Territory or the MERRIMACK Territory, as applicable; provided, however, that if the Parties fail to agree within an appropriate time period or if the matter involves a safety issue that, in order to protect patient safety, does not allow for sufficient time for a discussion at the JSC level (in which event the holder of the Drug Approval Application or Marketing Authorization for the Licensed Product at issue shall nonetheless provide advance notice and consultation with the other Party to the maximum practical extent prior to making a decision), either (i) [**] shall decide whether to recall or withdraw such

Licensed Product in the [**] Territory and shall undertake any such recall or withdrawal at its own cost and expense, except as may otherwise be provided in the MERRIMACK Supply Agreement, or (ii) [**] shall decide whether to recall or withdraw such Licensed Product in the [**] Territory and shall undertake any such recall or withdrawal at its own cost and expense, except as may otherwise be provided in the BAXTER Supply Agreement. Notwithstanding the foregoing, MERRIMACK's compliance with this Section 4.3 shall be subject to PharmaEngine's rights with respect to withdrawals and recalls of Licensed Product in the PharmaEngine Territory as set forth in Section 5.5 of the PharmaEngine Collaboration Agreement and MERRIMACK shall be responsible for any communication to PharmaEngine as required by Section 5.5 of the PharmaEngine Collaboration Agreement, provided that BAXTER shall not prevent or otherwise obstruct such communication and BAXTER shall cooperate to provide MERRIMACK with timely information as may be needed for MERRIMACK to comply with such obligations.

Section 4.4 <u>Pharmacovigilance</u>; <u>Safety Data Reporting</u>. The collaboration between the Parties will involve exchanging safety information and adverse events for the Licensed Product. Therefore, the Parties agree to enter into negotiations to set up, if required, a detailed safety data exchange agreement (the "<u>SDEA</u>") in due time (i.e., prior to the start of clinical development or Commercialization by BAXTER) to arrange access by BAXTER to the pharmacovigilance database for the Licensed Product, which shall be owned by MERRIMACK, and any future pharmacovigilance exchange between the Parties when relevant (e.g., in the case where MERRIMACK is sponsoring clinical studies or co-developing Licensed Product(s)). Each Party shall ensure, through its JSC representatives or designated personnel, that the competent pharmacovigilance groups or personnel from such Party begin to negotiate and establish the appropriate SDEA no later than [**] months before BAXTER commences clinical development or Commercialization hereunder. The SDEA shall be negotiated in good faith between the pharmacovigilance departments of each Party. The SDEA shall define the roles and responsibilities of both Parties in terms of pharmacovigilance and define the detailed safety exchange required to permit compliance by both Parties with safety reporting requirements to Regulatory Authorities and other entities in their respective territories and ensure worldwide safety surveillance.

Section 4.5 <u>Regulatory Compliance</u>. Each Party agrees that in performing its obligations under this Agreement, (a) it shall comply in all material respects with all applicable FDA, EMA and MHLW requirements and standards, including FDA's and EMA's current Good Manufacturing Practices and Good Clinical Practices, and (b) it will not employ or use the services of any person that has been debarred under Section 306(a) or 306(b) of the US Federal Food, Drug, and Cosmetic Act or excluded by the US Department of Health and Human Services from participation in federal healthcare programs.

Article V Commercialization

Section 5.1 <u>Overview</u>. Subject to the terms and conditions of this Agreement and BAXTER's compliance with the Global Marketing and Commercialization Principles approved by the JSC, BAXTER will have sole responsibility for the Commercialization of Licensed Products in the Field in the Licensed Territory, including all costs and expenses relating thereto, and for booking sales of Licensed Products throughout the Licensed Territory.

Section 5.2 <u>Commercialization Reports</u>. With respect to each Licensed Product developed pursuant to this Agreement, commencing with the calendar year in which an application for Marketing Authorization is first filed with respect to such Licensed Product in any Licensed Sub-Territory, and for each subsequent calendar year thereafter, BAXTER shall provide to MERRIMACK for MERRIMACK's review and comment, within [**] days following the end of each [**] month period (i.e., [**]) during each calendar year during the Term, a written report setting forth in reasonable detail BAXTER's and its Affiliates' and sublicensees' (a) activities and progress during such preceding [**] month period related to the Commercialization of the Licensed Compound and Licensed Products, including [**].

Section 5.3 <u>Product Labeling</u>. To the extent permitted under applicable Laws, all Licensed Products sold in the Licensed Territory shall carry the BAXTER name and logo on the product label. If required by applicable Laws in any specific country or jurisdiction, all Licensed Products sold in such specific country or jurisdiction shall state on the product label and written promotional material that the Licensed Product is licensed from MERRIMACK.

Article VI <u>Diligence</u>; Right of First Negotiation

Section 6.1 <u>Diligence Obligations</u>; <u>Development and Commercialization Activities</u>.

- (a) BAXTER shall use Commercially Reasonable Efforts to research, develop, obtain all necessary Regulatory Approvals for and, upon receipt of such Regulatory Approvals, Commercialize the Licensed Product in each of the Licensed Sub-Territories, except to the extent BAXTER has terminated this Agreement with respect to a particular Licensed Sub-Territory pursuant to Section 12.4, in which case BAXTER will be relieved of its obligations to use Commercially Reasonable Efforts in such terminated Licensed Sub-Territory.
 - (b) BAXTER's obligations to use Commercially Reasonable Efforts under Section 6.1(a) hereof shall require and shall be deemed to be satisfied:
- (i) in the EU if BAXTER uses Commercially Reasonable Efforts to develop, obtain necessary Regulatory Approvals for and Commercialize [**] such Licensed Product for each indication for which the Licensed Product is being developed pursuant to the Global Development Plan in any [**] of the Major EU Countries;
- (ii) in the Licensed Asian Territory if BAXTER uses Commercially Reasonable Efforts to develop, obtain necessary Regulatory Approvals for and Commercialize (including by commercially launching within [**] days of receipt of Marketing Authorization) such Licensed Product for each indication for which the Licensed Product is being developed pursuant to the Global Development Plan in any [**] of the Major Asian Countries; and
- (iii) in the ROW Territory if BAXTER uses Commercially Reasonable Efforts to develop, obtain necessary Regulatory Approvals for and Commercialize (including by commercially launching within [**] days of receipt of Marketing Authorization) such Licensed Product for each indication for which the Licensed Product is being developed pursuant to the Global Development Plan in any [**] of the Major ROW Countries;

provided, however, that any particular subsection (i), (ii) or (iii) does not need to be satisfied in order to fully satisfy this Section 6.1(b) if BAXTER terminates this Agreement pursuant to Section 12.4 with respect to the Licensed Sub-Territory corresponding to such particular subsection, and further provided that successfully achieving Regulatory Approvals and Commercialization of Licensed Products as set forth in the foregoing shall not be required to satisfy the foregoing (i.e., the use of Commercially Reasonable Efforts to achieve the foregoing objectives will satisfy such obligations).

(c) BAXTER shall not be in breach of the obligations set forth in Section 6.1(a) to the extent that BAXTER's failure to develop, obtain necessary Regulatory Approvals for and Commercialize a Licensed Product results from (i) the occurrence of a supply failure or breach under the MERRIMACK Supply Agreement or any other failure of MERRIMACK to supply material amounts of Drug Product, (ii) any recall, withdrawal or field correction ordered by a Regulatory Authority or undertaken by BAXTER or MERRIMACK in accordance with this Agreement, or (iii) the occurrence of an event of force majeure (in which case the Parties shall have the rights and obligations set forth in Section 15.6).

Section 6.2 <u>Right of First Negotiation</u>. MERRIMACK hereby grants to BAXTER a right of first negotiation to obtain rights to MM-111, MM-141 and MM-302 (collectively, the "<u>ROFN Programs</u>", each a "<u>ROFN Programs</u>") outside of the US or with regard to any Licensing Opportunity (as defined below) that includes any territory outside of the US during the Term of this Agreement on the terms and conditions set forth in this Section 6.2.

- (a) If MERRIMACK intends to begin negotiations with a Third Party (other than contract research organizations, other services providers and other Third Parties to which MERRIMACK does not grant commercialization rights) to grant an exclusive or non-exclusive Commercialization license to such Third Party to develop and commercialize any ROFN Program in the Field outside of the US (the "Licensing Opportunity"), MERRIMACK shall provide written notice of such intent to BAXTER and BAXTER shall notify MERRIMACK in writing within [**] days (the "Response Period") as to whether BAXTER has a bona fide interest in discussing the Licensing Opportunity and wishes to receive further data and information relating to the Licensing Opportunity on a confidential basis. Such written notice from MERRIMACK shall include a reasonable summary of scientific data relevant to the use, safety, efficacy and any other matters as MERRIMACK can reasonably provide on a non-confidential basis relating to such Licensing Opportunity, to allow BAXTER to assess its interest in discussing the Licensing Opportunity.
- (b) If, before the expiration of the Response Period, BAXTER indicates in writing that it is interested in discussing the Licensing Opportunity, MERRIMACK shall provide BAXTER with confidential data and information within [**] days, and BAXTER shall have an additional [**] days (the "Additional Response Period") to notify MERRIMACK in writing as to whether BAXTER wishes to enter into exclusive negotiations with MERRIMACK regarding such Licensing Opportunity; provided, however, that the Additional Response Period may be extended by BAXTER for up to an additional [**] days if the Licensing Opportunity relates to more than one ROFN Program.

(c) If, before the expiration of the Additional Response Period, BAXTER indicates in writing that it is interested in entering into exclusive negotiations regarding the Licensing Opportunity, the Parties agree to negotiate a license to develop and Commercialize the ROFN Program in the Field outside of the US, exclusively, for a period of [**] days commencing on the date of BAXTER's indication of interest pursuant to this Section 6.2(c) (the "Negotiation Period"); provided, however, that the Negotiation Period may be extended by BAXTER for up to an additional [**] days if the Licensing Opportunity relates to more than one ROFN Program.

(d) If:

- (i) BAXTER does not indicate before the expiration of the Response Period or the Additional Response Period, as the case may be, that it is interested in discussing the Licensing Opportunity;
- (ii) BAXTER indicates before the expiration of the Response Period or the Additional Response Period, as the case may be, that it has no interest in the Licensing Opportunity; or
- (iii) BAXTER indicates such an interest before the expiration of the Response Period and Additional Response Period but the Parties do not enter into a definitive agreement with respect to the Licensing Opportunity prior to the expiration of the Negotiation Period;
- then BAXTER's right to negotiate the terms of, or enter into an agreement with respect to, the Licensing Opportunity with MERRIMACK under this Section 6.2 shall terminate and have no further force or effect, and MERRIMACK shall be free to negotiate and enter into a transaction relating to the Licensing Opportunity with any Third Party(-ies).
- (e) In consideration of the rights granted to BAXTER and MERRIMACK's obligations as set forth in this Agreement, including the rights granted to BAXTER under this Section 6.2, BAXTER agrees to the restrictions described in Exhibit E.

Article VII Grant of Licenses

- Section 7.1 <u>License Grants from MERRIMACK to BAXTER</u>. Subject to the terms and conditions of this Agreement, including Section 7.2(b), MERRIMACK hereby grants to BAXTER:
- (a) a royalty-bearing, exclusive right and license under the Licensed Intellectual Property, to research, have researched, develop, have developed, make, have made, use, offer for sale, sell, have sold and import the Licensed Compound and Licensed Products in the Field in the Licensed Territory, provided that MERRIMACK reserves the right to (i) conduct research and development activities in the Licensed Territory solely to support the research, development and Commercialization of the Licensed Compound and Licensed Products in the MERRIMACK Territory, and (ii) manufacture the Licensed Compound and Licensed Products inside the Licensed Territory solely for use and distribution in the MERRIMACK Territory; and

(b) a royalty-bearing, non-exclusive right and license in the Field in the MERRIMACK Territory under the Licensed Intellectual Property and counterparts thereto in the MERRIMACK Territory Controlled by MERRIMACK, (i) to the extent necessary for BAXTER to perform its obligations under the Global Development Plan, and (ii) to research, develop and manufacture (or have manufactured) the Licensed Compound and Licensed Products in the MERRIMACK Territory solely in support of research, development and Commercialization of the Licensed Compound and Licensed Products within the Licensed Territory.

The licenses granted to BAXTER under this Section 7.1 shall be (i) sublicenseable by BAXTER only in accordance with Section 7.3(a) and Section 7.3(c) and (ii) transferable by BAXTER only in accordance with Section 15.2.

Section 7.2 <u>License Grants from BAXTER to MERRIMACK</u>. Subject to the terms and conditions of this Agreement, including Section 7.1(b), BAXTER hereby grants to MERRIMACK:

- (a) a fully paid-up, royalty-free, exclusive right and license under the BAXTER Intellectual Property that is related to the Licensed Compound and Licensed Products and developed during the Term, to research, have researched, develop, have developed, make, have made, use, offer for sale, sell, have sold, import and export the Licensed Compound and Licensed Products in the Field in the MERRIMACK Territory, provided that BAXTER reserves the right to (i) conduct research and development activities in the MERRIMACK Territory solely to support the research, development and commercialization of the Licensed Compound and Licensed Products in the Licensed Territory, and (ii) manufacture the Licensed Compound and Licensed Products in the MERRIMACK Territory solely for use and distribution within the Licensed Territory; and
- (b) a fully paid-up, royalty-free, non-exclusive right and license in and outside the Field in the Licensed Territory under the BAXTER Intellectual Property that is related to the Licensed Compound and Licensed Products and developed during the Term, (i) to the extent necessary for MERRIMACK to perform its obligations under the Global Development Plan, and (ii) to research, develop and manufacture the Licensed Compound and Licensed Products in the Licensed Territory solely in support of research, development and Commercialization of the Licensed Compound and Licensed Products in the MERRIMACK Territory.

The licenses granted to MERRIMACK under this Section 7.2 shall be (i) sublicenseable by MERRIMACK only in accordance with Section 7.3(b) and Section 7.3(c) and (ii) transferable by MERRIMACK only in accordance with Section 15.2.

Section 7.3 Sublicense Rights.

(a) On a country-by-country basis, prior to obtaining Marketing Authorization for the Licensed Product in any applicable country within the Major Asian Countries, Major EU Countries or Major ROW Countries, [**]. On a country-by-country basis, either (i) following receipt of Marketing Authorization for the Licensed Product in any applicable country within the Major Asian Countries, Major EU Countries or Major ROW Countries, or (ii) at any time after the Effective Date within any applicable country that is not a Major Asian Country, Major EU

Country or Major ROW Country, BAXTER shall have the right to sublicense any of its rights under Section 7.1. Any sublicense granted by BAXTER shall be subject to the terms of this Agreement, including Section 7.3(c).

- (b) Subject to the terms of this Agreement, including Section 7.3(c), MERRIMACK shall have the right to grant sublicenses of any of its rights under Section 7.2.
- (c) Any sublicense granted under this Agreement shall be pursuant to a written agreement that imposes on such sublicensee obligations that are at least as restrictive as all relevant restrictions and limitations set forth in this Agreement, including the confidentiality provisions of Article X and, in the case of BAXTER, to the extent applicable to the sublicensed rights, diligence obligations with respect to the sublicensed territory that are sufficient to enable BAXTER to satisfy its diligence obligations under Section 6.1. If either Party grants a sublicense to a Third Party as permitted by this Section 7.3, then such sublicensing Party shall provide the other Party prompt written notice thereof. The sublicensing Party shall provide the non-sublicensing Party with an executed copy of any such sublicense (redacted as the sublicensing Party may reasonably determine to protect confidential or commercially sensitive information, provided that the sublicensing Party may not redact any information that is necessary for the non-sublicensing Party to determine whether such sublicense meets the requirements of this Agreement). Except as otherwise agreed by the Parties in writing, each Party shall be jointly and severally responsible with its sublicensees to the other Party for failure by its sublicensees to comply with this Agreement. Any sublicense shall terminate upon the termination or expiration of this Agreement.

Section 7.4 Compliance with Third Party Agreements.

- (a) The grants by MERRIMACK under Licensed Intellectual Property set forth in Section 7.1 include the sublicense of certain Licensed Intellectual Property that is owned by PharmaEngine. BAXTER's rights and licenses under, or with respect to, Licensed Intellectual Property, including any prosecution or enforcement undertaken by the Parties pursuant to Article IX, are limited with respect to the rights granted to MERRIMACK under the PharmaEngine Collaboration Agreement and are subject to all applicable restrictions, limitations and obligations imposed on MERRIMACK or its sublicensees in Sections 4.2(b), 4.2(d), 4.4, 5.2(c), 5.4, 5.5, 8.3, 8.4(b) and 9.7 (the "Flow-Through Sections") of such PharmaEngine Collaboration Agreement; provided, however, if the Flow-Through Sections require communication with PharmaEngine, that MERRIMACK shall be responsible for such communication but BAXTER shall not prevent or otherwise obstruct such communication and BAXTER shall cooperate to provide MERRIMACK with timely information as may be needed for MERRIMACK to comply with such obligations. BAXTER shall comply, and cause its Affiliates and sublicensees to comply, with all of the Flow-Through Sections. For the avoidance of doubt, the Flow-Through Sections specifically do not include any payment obligations.
- (b) The Flow-Through Sections of the PharmaEngine Collaboration Agreement shall be deemed to be included in this Agreement and BAXTER shall cooperate with MERRIMACK as reasonably requested by MERRIMACK to enable MERRIMACK to comply with such provisions.

- (c) MERRIMACK shall be solely responsible for paying all amounts due pursuant to the PharmaEngine Collaboration Agreement; provided, however, that if MERRIMACK fails to pay amounts due under the PharmaEngine Collaboration Agreement as a consequence of BAXTER failing to pay amounts payable by BAXTER to MERRIMACK hereunder in breach of this Agreement (which failure to pay materially contributes to MERRIMACK's inability to pay PharmaEngine), then MERRIMACK shall not have any liability to BAXTER hereunder for MERRIMACK's failure to pay such amounts.
- (d) Upon a claim of breach of the PharmaEngine Collaboration by PharmaEngine, MERRIMACK and BAXTER shall discuss in good faith a mutually agreeable solution to remedy such claim of breach which solution may, if mutually agreed by the Parties, include the assumption by BAXTER and/or one of its Affiliates of the obligation to make any required payments related to the Licensed Technology and Licensed Patent Rights directly to PharmaEngine. MERRIMACK shall indemnify BAXTER for any such amounts paid by BAXTER to PharmaEngine, which may, at BAXTER's option, be credited against any amounts otherwise due or payable in the future from BAXTER to MERRIMACK hereunder.
- Section 7.5 <u>Retained Rights</u>. Notwithstanding the rights and licenses granted to BAXTER in Section 7.1, MERRIMACK retains rights under the Licensed Technology and Licensed Patent Rights to the extent necessary for MERRIMACK to perform its obligations and exercise its rights under this Agreement.
- Section 7.6 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party grants to the other Party any license, express or implied, under its intellectual property rights.

Section 7.7 <u>Section 365(n) of the Bankruptcy Code</u>. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code.

Article VIII Financial Provisions

Section 8.1 <u>Upfront Payment</u>. BAXTER shall pay to MERRIMACK a one-time, non-refundable, non-creditable fee of One Hundred Million Dollars (US\$100,000,000) within [**] Business Days of the Effective Date.

Section 8.2 Research and Development Milestones

(a) BAXTER shall pay to MERRIMACK the following amounts for achievement of the following milestones:

	Research and Development Milestone Event	US Dollars	
(i)	[**]	\$	[**]
(ii)	[**]	\$	[**]
(iii)	[**]	\$	[**]
(iv)	[**]	\$	[**]
(v)	[**]	\$	[**]
	TOTAL	\$100,00	0,000

(b) Each milestone payment set forth in this Section 8.2 shall be payable by BAXTER upon the achievement of the related milestone event by MERRIMACK or any of its Affiliates, and MERRIMACK shall provide notice to BAXTER promptly upon achievement of such milestone event within [**] days from such achievement. MERRIMACK shall prepare and provide BAXTER with a corresponding invoice and BAXTER shall pay MERRIMACK each such milestone payment within [**] days after receipt of such invoice.

(c) With respect to milestone events set forth in Section 8.2(a)(iii), Section 8.2(a)(iv) and Section 8.2(a)(v), the JSC shall determine prior to the initiation of each clinical study in the Global Development Plan whether such clinical study is intended to become a Pivotal Clinical Study. Notwithstanding the foregoing, if a clinical study is reflected in the Global Development Plan as a clinical study that is intended to provide the basis for an application for Marketing Authorization, then such clinical study shall be deemed to be a Pivotal Clinical Study. If a clinical study that was not considered to be a Pivotal Clinical Study upon first dosing becomes a Pivotal Clinical Study after the first dosing in such study, then the applicable milestone event shall be deemed achieved and become payable at such time.

Section 8.3 Regulatory Milestones.

(a) BAXTER shall pay to MERRIMACK the following amounts for achievement of the following milestones:

		First Indication	Second Indication	For Each of Two Other Indications on an indication-by- indication basis
	Regulatory Milestone Event		US Dollars	marcanon sasis
(i)	[**]	[**]	[**]	[**]
(ii)	[**]	[**]	[**]	[**]
	[**]			
(iii)	[**]	[**]	[**]	[**]
	[**]			
(iv)	[**]	[**]	[**]	[**]
	[**]			
(v)	[**]	[**]	[**]	[**]
	[**]			
(vi)	[**]	[**]	[**]	[**]
	[**]			
(vii)	[**]	[**]	[**]	[**]
	TOTAL	\$120,000,000	\$200,000,000	\$100,000,000 per indication, up to a maximum of \$200,000,000

⁽b) With respect to the milestone events for the First Indication, if [**], then (i) the milestone set forth in Section 8.3(a)(ii) for the First Indication shall be reduced from \$[**] and (ii) the milestone payment set forth in Section 8.3(a)(iii) for the First Indication shall be reduced from \$[**] to \$[**]. Upon the [**], the amount of \$[**] shall be paid to MERRIMACK in accordance with this Section 8.3.

⁽c) Each milestone payment set forth in this Section 8.3 shall be payable by BAXTER upon the achievement of the related milestone event by BAXTER or any of its Affiliates or sublicensees, and BAXTER shall provide notice to MERRIMACK promptly upon achievement of such milestone event within [**] days from such achievement. Upon receipt of BAXTER's notice that a milestone event has been achieved or achievement by MERRIMACK or its Affiliates of a milestone event, MERRIMACK shall prepare and provide BAXTER with the corresponding invoice and BAXTER shall pay MERRIMACK each such milestone payment within [**] days after receipt of such invoice.

(d) With respect to the regulatory events set forth in clause (i) of the table set forth in Section 8.3(a) above, the Parties acknowledge that they anticipate that [**]. Notwithstanding the foregoing, in the event that [**], the regulatory event set forth in clause (i) of the table set forth in Section 8.3(a) above shall be deemed to have been achieved upon the [**].

Section 8.4 Sales Milestones.

(a) As to each Licensed Product, BAXTER shall pay MERRIMACK the following one-time Net Sales milestones, on a Licensed Product-by-Licensed Product basis:

Sales	US Dollars	
(i)	Total Licensed Territory Net Sales for such Licensed Product exceed \$[**] in any four (4) consecutive calendar quarters	[**]
(ii)	Total Licensed Territory Net Sales for such Licensed Product exceed $[**]$ in any four (4) consecutive calendar quarters	[**]
(iii)	Total Licensed Territory Net Sales for Licensed Product exceed \$[**] in any four (4) consecutive calendar quarters	[**]
(iv)	Total Licensed Territory Net Sales for Licensed Product exceed \$[**] in any four (4) consecutive calendar quarters	[**]
	TOTAL	\$250,000,000

(b) Each milestone payment set forth in Section 8.4(a) shall be payable by BAXTER only one time upon the achievement of the related milestone event by BAXTER and its Affiliates or sublicensees, and BAXTER shall provide notice to MERRIMACK of such achievement concurrently with BAXTER's royalty report pursuant to Section 8.5(e) for the calendar quarter in which such milestone event is achieved. BAXTER shall pay MERRIMACK each such milestone payment together with BAXTER's royalty payment pursuant to Section 8.5(e) for the calendar quarter in which the related milestone event is achieved.

(c) For purposes of clarity, more than one of the Net Sales milestones set forth above may be earned in the same four (4) consecutive calendar quarter period with respect to a Licensed Product. For example, if total Licensed Territory Net Sales with respect to a given Licensed Product have not achieved any of the lower sales milestone thresholds set forth in clause (i) or (ii) of Section 8.4(a) above in any previous four (4) consecutive calendar quarter period, but total Licensed Territory Net Sales with respect to such Licensed Product exceed \$[**] in a subsequent four (4) consecutive calendar quarter period, then all three milestone payments, totaling \$[**], payable upon achievement of the sales milestone thresholds set forth in clause (i), (ii) and (iii) of Section 8.4(a) above shall become payable to MERRIMACK hereunder.

Section 8.5 Royalties.

(a) <u>Royalty Rate for Licensed Territory</u>. As to each Licensed Product sold in the Licensed Territory, subject to adjustment under the remainder of this Section 8.5, BAXTER shall pay MERRIMACK royalties on aggregate annual (calendar year) Net Sales of such Licensed Product in the Licensed Territory, at the incremental royalty rates set forth below, on a Licensed Product-by-Licensed Product basis:

Aggregate Annual Net Sales (in US Dollars) for such Licensed Product in the Licensed Territory	Royalty Rates as a Percentage (%) of Net Sales
Portion of calendar year Net Sales up to and including \$[**]	[**]
Portion of calendar year Net Sales that exceeds $\{**\}$, up to and including $\{**\}$	[**]
Portion of calendar year Net Sales that exceeds \$[**], up to and including \$[**]	[**]
Portion of calendar year Net Sales that exceeds \$[**]	[**]

For example, if aggregate annual Net Sales of a given Licensed Product in the Licensed Territory for a given calendar year are US\$[**], then the royalty payable to MERRIMACK on such Net Sales of such Licensed Product in the Licensed Territory under this Section 8.5(a) for that year would be US\$[**], which is calculated as follows: [**].

(b) <u>Royalty Term</u>. BAXTER's obligation to pay the applicable royalties payable to MERRIMACK under Section 8.5(a) above (as the royalty rates applicable under each of the foregoing may be reduced by Section 8.5(c)) shall expire on a country-by-country and Licensed Product-by-Licensed Product basis, upon the latest of (i) the last to expire Valid Claim of a Licensed Patent (including, for the avoidance of doubt, any Joint Patent Rights) in such country that Covers the manufacture, Commercialization or therapeutic use of such Licensed Product in the Licensed Field in such country, taking into consideration all applicable patent extensions, (ii) the expiration of all applicable Regulatory Exclusivity for such Licensed Product in the Licensed Field in such country, or (iii) ten (10) years from the First Commercial Sale of such Licensed Product in such country (the "Royalty Term").

(c) Third Party Licenses.

(i) <u>Third Party License Costs</u>. Subject to Section 8.5(c)(iii), BAXTER shall be responsible for the costs, including royalties, milestones and fees, of all Third Party licenses entered into by BAXTER with Third Parties after the Effective Date. If BAXTER, in the opinion of reputable patent counsel, is required to obtain a license under any Third Party Patent Rights in order to manufacture, use, offer for sale, sell or import the Licensed Compound or Licensed Products in the Licensed Territory hereunder (each such arrangement, a "<u>Third Party License</u>"), and the costs, including royalties, milestones and fees, of all such Third Party Licenses ("<u>Third Party License Costs</u>"). The Parties agree that BAXTER shall take the

lead in negotiating and entering into any Third Party Licenses after the Effective Date, provided that [**] percent ([**]%) of the Third Party License Costs directly paid by BAXTER to the applicable licensors shall be subject to deduction by BAXTER pursuant to Section 8.5(c)(iii), and provided further that in the case of Third Party License Costs that are not payable solely with respect to the Licensed Compound or Licensed Products, BAXTER shall only be permitted to deduct the portion of such Third Party License Costs reasonably allocated to the Licensed Compound or Licensed Products.

- (ii) <u>Royalty Stacking</u>. Subject to Section 8.5(c)(iii), BAXTER may deduct from any royalties that are subsequently due to MERRIMACK under this Agreement, on a Licensed Product-by-Licensed Product and country-by-country basis, up to [**] percent ([**]%) of any Third Party License Costs actually paid by BAXTER pursuant to Section 8.5(c)(i) above to BAXTER's Third Party licensor(s) with respect to the Licensed Compound or Licensed Products in the Licensed Territory.
- (iii) <u>Limitation on Aggregate Deduction</u>. Notwithstanding Section 8.5(c)(i) and Section 8.5(c)(ii), in no event shall the amount of any royalties payable to MERRIMACK pursuant to Section 8.5(a) be reduced to less than [**] percent ([**]%) of the amounts specified in Section 8.5(a), for the applicable calendar quarter, as a result of all reductions made under this Section 8.5; provided, however, any reductions of royalties for Third Party License Costs that are limited by this Section 8.5(c)(iii) shall be offset, subject to this Section 8.5(c)(iii), against future royalties payable to MERRIMACK in subsequent quarters.
 - (d) Royalties Payable Only Once. The obligation to pay royalties is imposed only once with respect to the same unit of a Licensed Product.
- (e) <u>Royalty Reports and Payments</u>. BAXTER shall deliver to MERRIMACK, within [**] days after the end of each calendar quarter, a reasonably detailed written accounting of Net Sales of Licensed Products, and royalties and sales milestone payments, if any, due to MERRIMACK for such calendar quarter. Such quarterly reports shall indicate [**]. When BAXTER delivers such accounting to MERRIMACK, BAXTER shall also deliver all royalty payments due hereunder to MERRIMACK for the calendar quarter.
- Section 8.6 <u>Reconciliation and Payment of Development Costs.</u> Each Party shall pay to the other Party following the other Party's invoice, the paying Party's share of Development Costs and Manufacturing Costs incurred by the other Party in performing activities under the Global Development Plan pursuant to Article III in accordance with Section 8.9.

Section 8.7 Recordkeeping; Audit Rights.

(a) <u>Audits by MERRIMACK</u>. BAXTER shall keep, and shall require its Affiliates and sublicensees to keep, complete and accurate records of the latest [**] years of any Development Costs or Manufacturing Costs incurred in the conduct of development and manufacturing activities hereunder or sales of Net Sales of Licensed Products to which royalties or sales milestones attach hereunder. For the sole purpose of verifying amounts payable to or by MERRIMACK hereunder, MERRIMACK shall have the right [**] at MERRIMACK's expense to retain an independent certified public accountant selected by MERRIMACK and reasonably

acceptable to BAXTER, to review such records in the location(s) where such records are maintained by BAXTER, its Affiliates or its sublicensees upon reasonable notice and during regular business hours and under obligations of confidence. Results of such review shall be made available to both MERRIMACK and BAXTER. If the review reflects an underpayment of any amounts payable to MERRIMACK, such underpayment shall be remitted to MERRIMACK, within [**] days after the notification of the results and submission of an invoice by MERRIMACK to BAXTER, together with interest calculated in the manner provided in Section 8.10. If the underpayment is equal to or greater than [**] percent ([**]%) of the amount that was otherwise due, BAXTER shall pay all of the reasonable out of pocket expenses of such review. If the review reflects an overpayment of any amounts to MERRIMACK, the amount of such overpayment shall be refunded to BAXTER within [**] days of such review and submission of an invoice.

(b) <u>Audits by BAXTER</u>. MERRIMACK shall keep, and shall require its Affiliates and sublicensees to keep, complete and accurate records of the latest [**] years of any Development Costs or Manufacturing Costs incurred in the conduct of development and manufacturing activities hereunder, internal costs of MERRIMACK personnel at the applicable FTE Rate and out-of-pocket costs and expenses incurred by MERRIMACK in the conduct of research, development and regulatory activities under the Global Development Plan. For the sole purpose of verifying amounts payable to or by BAXTER hereunder, BAXTER shall have the right [**] at BAXTER's expense to retain an independent certified public accountant selected by BAXTER and reasonably acceptable to MERRIMACK, to review such records in the location(s) where such records are maintained by MERRIMACK, its Affiliates or its sublicensees upon reasonable notice and during regular business hours and under obligations of confidence. Results of such review shall be made available to both MERRIMACK and BAXTER. If the review reflects an underpayment of any amounts payable to BAXTER, such underpayment shall be remitted to BAXTER, within [**] days after notification of the results and submission of an invoice by BAXTER to MERRIMACK, together with interest calculated in the manner provided in Section 8.10. If the underpayment is equal to or greater than [**] percent ([**]%) of the amount that was otherwise due, MERRIMACK shall pay all of the reasonable out of pocket expenses of such review. If the review reflects an overpayment of any amounts to BAXTER, the amount of such overpayment shall be refunded to MERRIMACK within [**] days after such review and submission of an invoice.

Section 8.8 <u>Method of Payment</u>. All amounts payable by a Party hereunder shall be paid by or on behalf of such paying Party in US Dollars. With respect to sales of Licensed Products invoiced in US Dollars, the royalties payable to MERRIMACK shall be expressed in US Dollars. With respect to sales of Licensed Products invoiced in a currency other than US Dollars, the royalties payable shall be expressed in their US Dollar equivalent, calculated using the applicable conversion rates for buying US Dollars published by Bloomberg on the last Business Day of the calendar month in which such sales were made. All payments due to a Party hereunder shall be made by wire transfer directly to an account designated by such Party.

Section 8.9 <u>Invoices</u>. Unless otherwise expressly stated in this Agreement, MERRIMACK shall invoice BAXTER on a monthly basis for costs or expenses that become due and payable to MERRIMACK hereunder, including Development Costs and Manufacturing Costs, internal costs of MERRIMACK personnel at the applicable FTE Rate and out-of-pocket

costs and expenses incurred by MERRIMACK in the conduct of MERRIMACK's activities under this Agreement, Third Party License Costs and patent preparation, filing, prosecution and maintenance costs and expenses, and BAXTER shall pay MERRIMACK such invoiced amount within [**] days following receipt thereof. The foregoing shall apply reciprocally with respect to any costs invoiced by BAXTER to MERRIMACK.

Section 8.10 <u>Late Payments</u>. Any payment under this Agreement that is not paid on or before the date such payment is due shall bear interest at the lesser of (a) [**] as announced on the date such payment is due, or (b) the highest rate permitted by applicable Laws, calculated on the number of days such payments are overdue and compounded monthly. In addition, the Party responsible for paying shall reimburse the payee Party for all costs and expenses, including attorneys' fees and legal expenses, incurred in the collection of late payments, provided that the foregoing shall not apply with respect to payments disputed in good faith by the paying Party unless the payee Party is successful in such dispute or the paying Party ceases to dispute such payments.

Section 8.11 Tax Withholding.

- (a) All payments under this Agreement shall be made without any deduction or withholding for or on account of any tax, except as set forth in this Section 8.11. The Parties agree to cooperate with one another and use reasonable efforts to minimize under applicable Law obligations for any and all income or other taxes required by Law to be withheld or deducted from any of the royalty and other payments made by or on behalf of a Party hereunder ("Withholding Taxes"). The applicable paying Party under this Agreement (the "Paying Party") shall, if required by Law, deduct from any amounts that it is required to pay to the recipient Party hereunder (the "Recipient Party") an amount equal to such Withholding Taxes, provided that the Paying Party shall give the Recipient Party reasonable notice prior to paying any such Withholding Taxes. Such Withholding Taxes shall be paid to the proper taxing authority for the Recipient Party's account and, if available, evidence of such payment shall be secured and sent to the Recipient Party within [**] days of such payment. The Paying Party shall, at the Recipient Party's cost and expense, do all such lawful acts and things and sign all such lawful deeds and documents as the Recipient Party may reasonably request to enable the Paying Party to avail itself of any applicable legal provision or any double taxation treaties with the goal of paying the sums due to the Recipient Party hereunder without deducting any Withholding Taxes.
 - (b) Notwithstanding anything to the contrary herein:
 - (i) Either BII, BHC or BHSA will make all payments under this Agreement to MERRIMACK;
- (ii) based on MERRIMACK being a US corporation and thus, a resident of the United States as that term is defined in Article 4 of the US-Switzerland Income Tax Treaty, if BHSA makes any payment to MERRIMACK under this Agreement, BHSA will take the position that any such payment is treated for all tax purposes as being sourced in Switzerland and being a royalty exempt from Withholding Taxes pursuant to Article 12 of the US-Switzerland Income Tax Treaty, provided that MERRIMACK shall have provided BHSA on a timely basis with the documentation required to support such an exemption, and provided further there are no changes to the treaty that would affect the exemption; and

(iii) if there is an assignment of this Agreement by BAXTER or the payment of any amount hereunder by a party other than BAXTER that results in the imposition of a Withholding Tax then there will be an obligation on the party making such payment and BAXTER to increase or "gross up" any payments made hereunder so that the net amount paid, after deduction of Withholding Taxes, shall equal the amount that would have been paid if no Withholding Taxes had been imposed.

Section 8.12 <u>Blocked Payments</u>. In the event that, by reason of applicable Laws in any country, it becomes impossible or illegal for BAXTER or its Affiliates or sublicensees, to transfer, or have transferred on its behalf, royalties or other payments to MERRIMACK, such royalties or other payments shall be deposited in local currency in the relevant country to the credit of MERRIMACK in a recognized banking institution designated by MERRIMACK or, if none is designated by MERRIMACK within a period of [**] days, in a recognized banking institution selected by BAXTER or its Affiliates or sublicensees, as the case may be, and identified in a notice in writing given to MERRIMACK. The foregoing shall apply reciprocally to any payment that would be due by MERRIMACK to BAXTER hereunder.

Article IX <u>Intellectual Property Ownership, Protection and Related Matters</u>

Section 9.1 Ownership of Inventions

- (a) <u>Solely-Owned Inventions</u>. Each Party shall exclusively own all right, title and interest in and to all inventions made or conceived solely by the employees, agents, consultants or contractors of such Party or its Affiliates in the course of performing its activities under this Agreement and without relying on any Confidential Information received from the other Party.
- (b) <u>Joint Inventions</u>. All inventions made or conceived jointly by employees, agents and consultants of MERRIMACK or its Affiliates, and employees, agents, consultants or contractors of BAXTER or its Affiliates, shall be owned jointly on the basis of each Party having an undivided interest in the whole ("<u>Joint Inventions</u>"). Any invention made or conceived solely by one Party's employees, agents or contractors but relying on Confidential Information of the other Party shall also be deemed a Joint Invention. Subject to the licenses granted herein and each Party's payment obligations hereunder, each Party shall have the right to exploit such Joint Inventions without any duty to account to the other Party, provided that during the Term of this Agreement neither Party shall use or grant rights to any Third Party for Joint Inventions in the Field in relation to any nanoliposomal formulation of irinotecan for use in the Field.
- (c) <u>Inventorship</u>. For purposes of determining the Parties' rights under this Agreement, the determination of inventorship shall be made in accordance with US patent laws. In the event of any dispute regarding inventorship, if the Parties are unable to resolve the dispute, the Parties shall jointly engage mutually acceptable independent US patent counsel not regularly employed by either Party (or, if the Parties are unable to mutually agree on such patent counsel,

the New York, New York, US office of the CPR shall appoint such patent counsel) to resolve such dispute. The decision of such independent patent counsel shall be based upon evidence submitted by the Parties within a fixed time to be designated at the outset by such counsel and shall be binding on the Parties with respect to the issue of inventorship.

Section 9.2 Prosecution and Maintenance of Patent Rights.

- (a) Licensed Patent Rights Solely Controlled by MERRIMACK. Subject to any rights of and obligations to MERRIMACK's Third Party licensors with respect to Licensed Patent Rights not owned by MERRIMACK, MERRIMACK shall use Commercially Reasonable Efforts to prepare, file and prosecute any patent applications and to maintain any patents within the Licensed Patent Rights (other than any Joint Patent Right), in MERRIMACK's name, and to control any interference, opposition and similar proceedings relating thereto, in any patent jurisdictions requested by BAXTER, at BAXTER's expense, provided that each Party [**] of pre-nationalization expenses incurred by MERRIMACK in the preparation, filing and prosecution of provisional patent applications and Patent Cooperation Treaty ("PCT") patent applications within such Licensed Patent Rights in which both the US and country(-ies) of the Licensed Territory are designated. Subject to any rights of and obligations to MERRIMACK's Third Party licensors with respect to Licensed Patent Rights not owned by MERRIMACK, MERRIMACK shall inform and consult with BAXTER regarding the preparation, filing, prosecution, defense and maintenance of all such patent applications sufficiently in advance of any deadline for taking any substantive action in connection therewith to permit meaningful consultation, and shall give due consideration to any BAXTER suggestions or recommendations. By way of example and without limitation, each the following shall be considered a substantive action: preparing and/or filing an original application; canceling or amending claims; responding to an office action regarding unity of invention or on the merits (irrespective of whether claims are amended or canceled); filing a continuing application or request for continued examination; filing an appeal; filing an appeal brief; abandoning or withdrawing an application; allowing an application to lapse through inaction or nonpayment of fees; issuing notice letters to suspected infringers; bringing suit to enforce a pate
- (b) <u>BAXTER Patent Rights Solely Controlled by BAXTER</u>. BAXTER shall have the exclusive right and option (but not the obligation), at its sole cost and expense, to prepare, file and prosecute any patent applications and to maintain any patents within BAXTER Patent Rights (other than Joint Patent Rights) in BAXTER's name, and to control any interference, opposition and similar proceedings relating thereto.
- (c) <u>Joint Patent Rights</u>. MERRIMACK shall use Commercially Reasonable Efforts to prepare, file and prosecute any patent applications and to maintain any patents within the Joint Patent Rights, in both Parties' names, and to control any interference, opposition and similar proceedings relating thereto, in the US and any patent jurisdictions requested by BAXTER, at MERRIMACK's expense for the US and otherwise at BAXTER's expense, provided that each Party shall bear fifty percent (50%) of pre-nationalization expenses incurred by MERRIMACK in the preparation, filing and prosecution of provisional patent applications and PCT patent applications within such Joint Patent Rights in which both the US and country(-ies) of the Licensed Territory are designated. MERRIMACK shall inform and consult with BAXTER regarding the preparation, filing, prosecution, defense and maintenance of all such

Joint Patent Rights sufficiently in advance of any deadline for taking any substantive action in connection therewith to permit meaningful consultation, and shall give due consideration to any BAXTER suggestions or recommendations. By way of example and without limitation, each the following shall be considered a substantive action: preparing and/or filing an original application; canceling or amending claims; responding to an office action regarding unity of invention or on the merits (irrespective of whether claims are amended or canceled); filing a continuing application or request for continued examination; filing an appeal brief; abandoning or withdrawing an application; allowing an application to lapse through inaction or nonpayment of fees; issuing notice letters to suspected infringers; bringing suit to enforce a patent; and settling, dismissing or withdrawing such suit. In the event that MERRIMACK elects not to file, prosecute, or maintain, or elects to abandon any Joint Patent Right, or declines to control any related interference, opposition or similar proceedings, MERRIMACK shall give BAXTER reasonable written notice to this effect, sufficiently in advance to permit BAXTER, in its sole discretion and expense, to undertake such filing, prosecution and maintenance, or to control such interference, opposition or similar proceedings, without a loss of rights, and thereafter BAXTER may, upon written notice to MERRIMACK and jointly in both Parties' names, file, prosecute and maintain such Joint Patent Rights and control such interference, opposition or similar proceedings relating to the Patent Prosecution of any Joint Patent Rights, the other Party shall join as a party to such interference, opposition or similar proceedings.

- (d) <u>Invoicing and Payment of Costs and Expenses</u>. The Parties shall invoice one another for and pay their respective share of such costs and expenses for Licensed Patent Rights and Joint Patent Rights in accordance with Section 8.9.
- (e) <u>Cooperation</u>. Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of patents and patent applications pursuant to this Section 9.2 ("<u>Patent Prosecution</u>"), subject to any rights of, and obligations to, MERRIMACK's Third Party licensors, including the following actions:
- (i) executing all such documents and instruments and performing such acts as may be reasonably necessary in order to permit the other Party to continue any Patent Prosecution that such Party has elected not to pursue, as provided for in Section 9.2(c);
- (ii) making its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable the prosecuting Party to undertake Patent Prosecution;
- (iii) providing (itself or through patent counsel) the other Party a copy of each proposed material correspondence pertaining to substantive Patent Prosecution on the merits with the US Patent and Trademark Office ("<u>USPTO</u>"), the World Intellectual Property Office ("<u>WIPO</u>") or the European Patent Office ("<u>EPO</u>"), as well as providing draft copies of patent applications to be submitted to the USPTO or to the WIPO under the Patent Cooperation Treaty, or submitted to any patent office in the Licensed Territory in a form substantially different from that previously submitted to the USPTO or to the WIPO, reasonably in advance of any applicable filing or response deadline to allow the other Party to review and comment on the

content of such proposed correspondence and advise the prosecuting Party as to the conduct of such Patent Prosecution, which comments and advice the prosecuting Party will reasonably consider, provided that doing so is consistent with the goal of obtaining optimal patent coverage for Licensed Products;

(iv) providing (itself or through patent counsel) the other Party with copies of all material correspondence pertaining to substantive Patent Prosecution on the merits with the USPTO, the WIPO or the EPO after its submission or receipt, as the case may be; and

(v) seeking patent term extensions, adjustments and the like wherever available for the Licensed Patent Rights in the Licensed Territory.

Section 9.3 Third Party Infringement.

- (a) Notice. Each Party shall promptly report in writing to the other Party during the Term any known or suspected (i) infringement of any issued claims within the Licensed Patent Rights, or (ii) misappropriation of any of the Licensed Technology of which such Party becomes aware. In the event such known or suspected infringement or misappropriation involves the manufacture, use or Commercialization of a product or product candidate that is or may be competitive with the Licensed Compound or a Licensed Product being developed or Commercialized by BAXTER hereunder in the Licensed Territory ("Competitive Infringement"), the reporting Party shall provide the other Party with all available evidence supporting such infringement, suspected infringement, misappropriation or suspected misappropriation. Promptly after receipt of a notice of a Competitive Infringement, the Parties shall discuss in good faith the infringement and appropriate actions that could be taken to cause such infringement of Licensed Patent Rights or use of misappropriated Licensed Technology to cease.
- (b) Enforcement. Subject to any rights of and obligations to MERRIMACK's Third Party licensors, BAXTER shall have the first right to initiate a suit or take other appropriate action that it believes is reasonably required to protect (i.e., prevent or abate actual or threatened misappropriation or infringement of, or otherwise enforce, in the best commercial interests of Licensed Products) the Licensed Intellectual Property (including Joint Patent Rights and Joint Technology) against any Competitive Infringement, at BAXTER's sole control and expense. If BAXTER fails to initiate a suit or take other appropriate action that it has the initial right to initiate or take to protect the Licensed Intellectual Property against any Competitive Infringement within [**] days (or such shorter period specified below in this Section 9.3(b) or in Section 9.6, if applicable) after becoming aware of the basis for such suit or action, then MERRIMACK may, in its discretion, initiate a suit or take other appropriate action that it believes is reasonably required to protect the Licensed Intellectual Property at issue. The [**] day period in the immediately preceding sentence shall be shortened as reasonably necessary to enable MERRIMACK to initiate a suit or take other appropriate action if, in the absence of such shortening, a loss of rights with respect to such suit or other action would occur. The Party filing any such suit or taking any such action shall be responsible for all costs in connection therewith and, therefore, shall control all decision-making related to any such suit or action, subject to Section 9.3(c) below.

(c) Conduct of Actions. The Party initiating suit or action shall have the sole and exclusive right to select counsel for any suit initiated by it referred to in Section 9.3(b) above. If required under applicable Laws in order for the initiating Party to initiate or maintain such suit or action, the other Party shall join as a party to the suit or action. Such other Party shall offer reasonable assistance to the initiating Party in connection therewith [**] to the initiating Party except for reimbursement of reasonable out-of-pocket expenses incurred in rendering such assistance. The Party filing any such suit or taking any such action shall provide the other Party with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, the Party filing any such suit or taking any such action shall, to the extent permitted by applicable Laws, keep the other Party promptly informed, and shall from time to time consult with such other Party regarding the status of any such suit or action and shall provide such other Party with copies of all material documents (i.e., complaints, answers, counterclaims, material motions, orders of the court, memoranda of law and legal briefs, interrogatory responses, depositions, material filings, expert reports, affidavits filed in court, transcripts of hearings and trial testimony, trial exhibits and notices of appeal) filed in, or otherwise relating to, such suit or action. The Party not initiating such suit or action shall cooperate with the Party initiating such suit or action to the extent reasonably requested, and shall have the right to participate and be represented in any such suit by its own counsel at its own expense. Neither Party shall conduct any such suit or action in a manner that materially places at risk the scope or validity of any Licensed Patent Right without the prior written approval of the other Party, and neither Party shall settle or compromise any claim or proceeding relating to Licensed Intellectual Property without obtaining the

- (d) <u>Recoveries</u>. With respect to any suit or action to protect Licensed Intellectual Property referred to in Section 9.3(b) above, any recovery obtained as a result of any such proceeding, by settlement or otherwise, shall be applied in the following order of priority:
- (i) first, the Party initiating the suit or action with respect to Licensed Intellectual Property shall be reimbursed for all costs and expenses in connection with such proceeding paid by such Party and not otherwise recovered; and
- (ii) second, any remainder shall be paid [**] percent ([**]%) to the Party initiating such suit or action and [**] percent ([**]%) to the other Party.

Section 9.4 <u>Claimed Infringement</u>. In the event that a Party becomes aware of any claim or threat of claim that the research, development, manufacture or Commercialization of the Licensed Compound or any Licensed Product by MERRIMACK or BAXTER hereunder infringes in the Licensed Territory or misappropriates the intellectual property rights of any Third Party, such Party shall promptly notify the other Party. Each Party shall provide to the other Party copies of any notices it receives from Third Parties regarding any patent nullity actions, any declaratory judgment actions, any alleged infringement of Third Party Patent Rights or any alleged misappropriation of Third Party Know-How. Such notices shall be provided promptly, but in no event after more than [**] days following receipt thereof. In any such instance, the Parties shall cooperate in undertaking an appropriate course of action.

Section 9.5 Patent Invalidity Claim.

- (a) If a Third Party at any time asserts a claim that any Licensed Patent Right in the Licensed Territory is invalid or otherwise unenforceable ("Invalidity Claim"), whether as a defense in an infringement action brought by BAXTER or MERRIMACK pursuant to Section 9.3 or in an action brought against BAXTER or MERRIMACK under Section 9.4, including any declaratory judgment action, the Parties shall cooperate with each other in preparing and formulating a response to such Invalidity Claim. Neither Party shall settle or compromise any Invalidity Claim without the consent of the other Party, which consent shall not be unreasonably withheld.
- (b) If any Invalidity Claim is brought against BAXTER or MERRIMACK in any new action (and not as a defense in any action brought by BAXTER or MERRIMACK) asserting that any Licensed Patent Right is invalid or otherwise unenforceable, the Parties shall bear the costs of defending such Invalidity Claim in the same manner as they bear costs of Patent Prosecution pursuant to Section 9.2 unless the Invalidity Claim is brought against the same patent and in the same country where BAXTER or MERRIMACK has commenced an enforcement action against either the entity bringing the Invalidity Claim or an affiliate thereof. In the latter case the costs and recoveries, if any, will be shared as if they had been incurred in the enforcement action.

Section 9.6 <u>Certification Under Drug Price Competition and Patent Restoration Act</u>. If a Party becomes aware of any certification filed pursuant to any Law in any other jurisdiction in the Licensed Territory that is comparable to 21 U.S.C. §355(b)(2)(A)(iv) or §355(j)(2)(A)(vii)(IV), including any amendment or successor statute thereto, and such certification claims that any Licensed Patent Right or Joint Patent Right, in each case Covering the Licensed Compound or a Licensed Product in the Field in the Licensed Territory, is invalid or otherwise unenforceable, or that infringement will not arise from the manufacture, use, import or sale or offer of sale of a product by a Third Party, such Party shall promptly notify the other Party in writing within [**] Business Days after its receipt thereof.

Section 9.7 <u>Patent Marking</u>. BAXTER agrees to comply with the patent marking statutes in each country in which Licensed Products are sold by BAXTER, its Affiliates or sublicensees.

Article X Confidentiality

Section 10.1 Confidential Information. All Confidential Information disclosed by a Party or any of its Affiliates to the other Party or any of its Affiliates during the Term shall not be used by the receiving Party or any of its Affiliates except in connection with the activities contemplated by this Agreement, shall be maintained in confidence by the receiving Party and its Affiliates (except to the extent disclosure is reasonably necessary for research, development, manufacture or Commercialization of the Licensed Compound or a Licensed Product as contemplated hereunder, for the filing, prosecution and/or maintenance of Patent Rights for which such receiving Party is responsible, or to enforce the provisions of this Agreement), and shall not otherwise be disclosed by the receiving Party or its Affiliates to any Person that is not a Party or one of its Affiliates (except as set forth in the remainder of this Article X), without the prior written consent of the disclosing Party, except to the extent that the Confidential Information:

(a) was known or used by the receiving Party or any of its Affiliates prior to its date of disclosure to the receiving Party;

- (b) either before or after the date of the disclosure to the receiving Party hereunder is lawfully disclosed to the receiving Party or any of its Affiliates by sources other than the disclosing Party rightfully in possession of the Confidential Information;
- (c) either before or after the date of the disclosure to the receiving Party hereunder becomes published or generally known to the public through no fault or omission on the part of the receiving Party;
- (d) is independently developed by or for the receiving Party or any of its Affiliates without reference to or reliance upon the Confidential Information; or
- (e) is required to be disclosed by the receiving Party to comply with applicable Laws, including the rules of the Securities and Exchange Commission (the "SEC") or any stock exchange, or to defend or prosecute litigation or to comply with legal process, provided that the receiving Party provides prior written notice of such disclosure to the disclosing Party (to the extent feasible) and only discloses Confidential Information of the other Party to the extent necessary for such legal compliance or litigation purpose.

Section 10.2 Employee, Director, Consultant and Advisor Obligations. BAXTER and MERRIMACK each agrees that it and its Affiliates shall provide Confidential Information received from the other Party only to the receiving Party's respective employees, directors, consultants, agents and advisors, and to the employees, directors, consultants, agents and advisors of the receiving Party's Affiliates, who have a need to know such Confidential Information to assist the receiving Party in fulfilling its obligations under this Agreement and who are bound by obligations of confidentiality and non-use that are at least as restrictive as those set forth in this Agreement. Each Party shall remain responsible for any failure by any of such Party's Affiliates, employees, directors, consultants, agents and advisors to treat such Confidential Information as required under Section 10.1.

Section 10.3 <u>Publicity</u>. Upon execution of this Agreement, the Parties shall, at their discretion, either (a) jointly issue a mutually agreed upon press release announcing the execution of this Agreement or (b) issue separate press releases announcing the execution of this Agreement with the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed (the "<u>Initial Press Release</u>"). Except with respect to the Initial Press Release, or any other public disclosure with contents substantially similar thereto, no public disclosure shall be made by either Party concerning the execution of this Agreement or the terms and conditions hereof without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed. Each Party may issue press releases and public announcements concerning the development or Commercialization of a Licensed Product, provided that such Party shall provide the Alliance Manager of the other Party with a draft of such press release or public announcement at least

[**] days in advance of its intended publication or release thereof and shall consider in good faith the comments of the other Party, which comments shall be provided as promptly as reasonably practicable, but in no event more than [**] days, following receipt of the press release or public announcement from the Party desiring to make the disclosure. If the Parties are unable to agree on any proposed material modifications to the press release or public announcement, then the JSC (or at least one member of the JSC from each of MERRIMACK and BAXTER if not all JSC members are available) shall meet telephonically and attempt to resolve the disagreement within [**] days after receipt of the original comments. Notwithstanding the foregoing, [**], as applicable. Notwithstanding anything contained in this Section 10.3, neither Party will be prevented from complying on a timely basis with any duty of disclosure it may have pursuant to Law or pursuant to the rules of any recognized stock exchange or quotation system.

Section 10.4 <u>Other Disclosures</u>. Notwithstanding anything in this Agreement to the contrary, each Party shall have the right to disclose Confidential Information and/or the terms of this Agreement (as applicable):

- (a) to investors, potential investors, lenders, potential lenders, acquirers, potential acquirers, investment bankers and other Third Parties in connection with financing, partnering and acquisition activities, solely under obligations of confidentiality and non-use that are at least as restrictive as those set forth in this Article X;
- (b) to sublicensees, potential sublicensees, collaborators, potential collaborators and Third Party contractors for purposes of engaging in the research, development, manufacture or Commercialization of the Licensed Compound or Licensed Products as contemplated hereunder, solely under obligations of confidentiality and non-use that are at least as restrictive as those set forth in this Article X; and
- (c) as required by applicable Laws, including rules of the SEC or similar regulatory agency in a country other than the US or of any stock exchange or other securities trading institution. In the event that this Agreement shall be included in any report, statement or other document filed by either Party or an Affiliate of either Party with the SEC or similar regulatory agency in a country other than the US or any stock exchange or other securities trading institution, such Party shall use, or shall cause such Party's Affiliate, as the case may be, to use, reasonable efforts to obtain confidential treatment from the SEC, similar regulatory agency, stock exchange or other securities trading institution of any financial information or other information of a competitive or confidential nature, and shall use reasonable efforts to include in such confidentiality request such provisions of this Agreement as may be reasonably requested by the other Party.

Section 10.5 Publications.

(a) A Party seeking to publish or present scientific or technical data, results or other information with respect to the Licensed Compound or any Licensed Product (the "Publishing Party.") shall provide the other Party and the Alliance Managers with a copy of any proposed publication or presentation at least [**] days (or at least [**] days in the case of abstracts or oral presentations) prior to submission for publication by the Publishing Party or its

Affiliates so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement or to not jeopardize the patentability of any results or data.

- (b) If the non-Publishing Party notifies the Publishing Party that such publication or presentation, in the non-Publishing Party's reasonable judgment, (i) contains an invention for which such Party desires to obtain patent protection, or (ii) contains any Confidential Information of such Party, or could be expected to have an adverse effect on the commercial value of any Confidential Information disclosed by such Party to the Publishing Party, the Publishing Party shall delete such Confidential Information from the proposed publication or presentation and shall further delay such publication or presentation for a period reasonably sufficient to permit the timely preparation and filing of a patent application(s) on any invention disclosed in such publication or presentation (but no less than [**] days from the date of the non-Publishing Party's notice thereof).
- (c) The JSC or designated working group shall be responsible for overseeing and facilitating the Parties' communications and activities with respect to publications and presentations under this Section 10.5, and for serving as the initial forum for resolving any disputes (in accordance with Section 2.1(e) between the Parties arising under this Section 10.5, with any unresolved disputes being escalated to the Executive Officers for resolution pursuant to Section 13.1).

Section 10.6 <u>Clinical Trial Registry</u>. Each of BAXTER and MERRIMACK shall have the obligation to the extent required by applicable Laws or regulations to publish summaries of data and results from any human clinical trials conducted by such Party under this Agreement on its clinical trials registry or on a government-sponsored database such as www.clinicaltrials.gov or other publicly available websites such as www.clinicalstudyresults.org, without requiring the consent of the other Party. The content of such publication shall be submitted to the JSC or designated working group for prior approval.

Section 10.7 <u>Confidentiality Term</u>. All obligations of confidentiality imposed under this Article X shall expire [**] years following termination or expiration of this Agreement.

Article XI Representations and Warranties

Section 11.1 <u>Representations and Warranties of Both Parties</u>. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

- (a) such Party is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- (b) such Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

(c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof;

- (d) the execution, delivery and performance of this Agreement by such Party does not conflict with any agreement or any provision thereof, or any instrument or binding understanding, oral or written, to which it is a party or by which it is bound, nor to the best of its knowledge violate any law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party; and
- (e) no government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any applicable Laws currently in effect, is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection herewith, or for the performance by it of its obligations under this Agreement and such other agreements to conduct clinical trials or to seek or obtain Marketing Authorizations.
- Section 11.2 <u>Representations and Warranties of MERRIMACK</u>. MERRIMACK hereby represents and warrants to BAXTER, as of the Effective Date, that, except as MERRIMACK has disclosed to BAXTER as of the Effective Date:
 - (a) MERRIMACK is the owner of, or has Control of, the Licensed Patent Rights listed on Exhibit B;
- (b) Exhibit B is a complete and correct list of all Licensed Patent Rights that claim or are directed to MM-398 and are Controlled by MERRIMACK as of the Effective Date;
- (c) MERRIMACK has the right to grant all rights and licenses it purports to grant to BAXTER with respect to the Licensed Intellectual Property under this Agreement;
- (d) MERRIMACK has not granted, as of the Effective Date, any right or license, to any Third Party relating to any of the Licensed Intellectual Property in the Licensed Territory, that would conflict with, or limit the scope of, any of the rights or licenses granted to BAXTER hereunder;
- (e) To MERRIMACK's knowledge, it has not (i) employed or used any contractor or consultant that employs any individual or entity debarred by the FDA (or subject to a similar sanction of EMA) or (ii) employed any individual or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA);
- (f) As of the Effective Date, there is no written allegation of, and there is no pending or, to MERRIMACK's knowledge, threatened claim, litigation or any other proceeding brought by a Third Party that any of the Licensed Patent Rights is invalid or unenforceable or that any Patent Right within the Licensed Patent Rights is subject to interference, reexamination, reissue, revocation, opposition, appeal or other administrative proceedings;

(g) To the knowledge of MERRIMACK, the research, development, manufacture, use and/or sale as of the Effective Date of MM-398 in the Licensed Territory as a therapeutic in the Field can be carried out in the manner contemplated by this Agreement without infringing any Patent Right Controlled by a Third Party;

- (h) To the Knowledge of MERRIMACK Management, MERRIMACK has provided all Freedom to Operate Opinions applicable to MM-398 and the Licensed Patent Rights in the Licensed Territory as of the Effective Date;
- (i) MERRIMACK has not received, with respect to the Licensed Patent Rights or the Licensed Technology, any written notice of infringement or misappropriation or any other written communication relating to a possible infringement or misappropriation of any Patent Right or any know-how Controlled by a Third Party;
- (j) The Licensed Patent Rights listed in <u>Exhibit B</u> represent all Patent Rights within MERRIMACK's Control necessary for the development, manufacture and Commercialization of the a Licensed Product in the Licensed Territory;
- (k) The Patent Rights listed on Exhibit B (solely as to the knowledge of MERRIMACK as to Patent Rights not owned by MERRIMACK) have been filed in good faith, have been prosecuted in accordance with any applicable duty of candor, and have been maintained in a manner consistent with MERRIMACK's or its licensor's standard practice, in each applicable jurisdiction in which such Patent Rights have been filed, no official final deadlines with respect to prosecution thereof have been missed and all applicable fees have been paid on or before the due date for payment;
- (l) All inventors of inventions claimed in the Licensed Intellectual Property listed on Exhibit B (solely as to the knowledge of MERRIMACK as to Patent Rights not owned by MERRIMACK) have assigned (and all current MERRIMACK employees are subject to a policy or agreement that requires them to assign) their entire right, title and interest in and to such inventions to MERRIMACK or MERRIMACK's licensor, the inventors listed are correct and MERRIMACK is aware of no claims or assertions regarding the inventorship of such Patent Rights alleging that additional or alternative inventors ought to be listed;
- (m) MERRIMACK has taken reasonable measures to protect the confidentiality of the Licensed Technology, and, to MERRIMACK's best knowledge, no event has occurred which has resulted in the unauthorized use or disclosure of the Licensed Technology by MERRIMACK or its personnel of any material part of the Licensed Technology or which otherwise resulted in any material part of the Licensed Technology entering the public domain; and
- (n) MERRIMACK is not in breach of the PharmaEngine Collaboration Agreement and the PharmaEngine Collaboration Agreement is in full force and effect.
 - Section 11.3 Mutual Covenants. Each Party hereby covenants to the other Party that:
- (a) All employees of such Party or its Affiliates working under this Agreement will be under the obligation to assign all right, title and interest in and to their

inventions and discoveries arising in the performance of such work, whether or not patentable, to such Party as the sole owner thereof, either immediately upon invention or, if applicable Law so provides, upon disclosure to and demand made by such Party;

- (b) To its knowledge, such Party will not (i) employ or use any contractor or consultant that employs any individual or entity debarred by the FDA (or subject to a similar sanction of EMA) or (ii) employ any individual who or entity that is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA), in each of clauses (i) and (ii) in the conduct of its activities under this Agreement;
 - (c) Such Party shall perform its activities pursuant to this Agreement in compliance in all material respects with applicable Laws; and
- (d) Neither Party shall, during the Term, grant any right or license to any Third Party relating to any of the intellectual property rights it owns or Controls which would conflict with, or limit the scope of, any of the rights or licenses granted or to be granted to the other Party hereunder.

Section 11.4 <u>DISCLAIMER</u>. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, EACH PARTY DISCLAIMS ANY WARRANTIES WITH REGARDS TO: (A) THE SUCCESS OF ANY STUDY OR TEST COMMENCED UNDER THIS AGREEMENT, (B) THE SAFETY OR USEFULNESS FOR ANY PURPOSE OF THE TECHNOLOGY OR MATERIALS, INCLUDING ANY COMPOUNDS, IT PROVIDES OR DISCOVERS UNDER THIS AGREEMENT, OR (C) THE VALIDITY, ENFORCEABILITY OR NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OR TECHNOLOGY IT PROVIDES OR LICENSES TO THE OTHER PARTY UNDER THIS AGREEMENT.

Article XII Term and Termination

Section 12.1 <u>Term</u>. This Agreement shall become effective as of the Effective Date, may be terminated as set forth in this Article XII, and otherwise remains in effect until the expiration of the Royalty Term in the Licensed Territory and satisfaction of the applicable payment obligations of BAXTER (including milestone payments) under this Agreement (the "Term").

Section 12.2 <u>Survival of Licenses</u>. Notwithstanding anything herein, on a Licensed Product-by-Licensed Product and country-by-country basis, upon the expiration (but not the earlier termination) of all royalty payment obligations for a Licensed Product in a country, the licenses granted to BAXTER in Section 7.1 shall be deemed to be perpetual and fully paid-up with respect to such Licensed Product in such country.

Section 12.3 Termination For Material Breach. Upon any material breach of this Agreement by either Party (in such capacity, the "Breaching Party"), the other Party (in such capacity, the "Non-Breaching Party") may terminate this Agreement by providing [**] days' prior written notice ([**] days' prior written notice with respect to any payment breach) to the Breaching Party, specifying the material breach. The termination shall become effective at the end of the [**] day (or, with respect to any payment breach, [**] day) period unless (a) the Breaching Party cures such breach during such [**] day (or, with respect to any payment breach, [**] day) period unless (a) the Breaching Party cures such breach during such [**] day (or, with respect to any payment breach, [**] day) period (unless the Party owing payment believes in good faith that such payment is not due and has notified the other Party thereof (including the basis of its good faith belief in reasonable detail) and paid any undisputed amount to the other Party, in which case the dispute shall be settled in accordance with Article XIII, and this Agreement shall not be terminated as long as the dispute is pending), or (b) solely with respect to a breach that is not a payment breach, if such breach is not susceptible to cure within [**]) days of the receipt of written notice of the breach, the Breaching Party is diligently pursuing a cure (unless such breach, by its nature, is incurable, in which case this Agreement may be terminated immediately) and effects such cure within an additional [**] days after the end of such [**] day period. It is understood and agreed that a private, non-public request to amend or waive a restriction set forth in Exhibit E communicated by a senior executive at BAXTER only to a senior executive of MERRIMACK and which MERRIMACK reasonably determines, after consultation with legal counsel, does not require public disclosure by MERRIMACK pursuant to applicable Law shall not constitute a material breach of this Agreement; provided, h

Section 12.4 <u>Termination by BAXTER for Convenience</u>. BAXTER shall have the right to terminate this Agreement, with respect to (a) one or more Licensed Products, (b) one or more country or countries, (c) one or more Licensed Sub-Territory(-ies) and/or (d) in its entirety, at any time for any reason upon one hundred eighty (180) days prior written notice, provided that, after receiving such notice, MERRIMACK shall have the right to elect, in MERRIMACK's sole option and discretion and by written notice to BAXTER, to accelerate such termination period to a date specified by MERRIMACK. For clarity, other than BAXTER's obligations explicitly set forth in Section 12.6 (or Section 12.7 as applicable) and Section 12.8, but without limiting BAXTER's obligations or liability for any breach of Section 6.1, no compensation whatsoever shall be due by BAXTER by reason of termination under this Section 12.4. If BAXTER terminates this Agreement in accordance with this Section 12.4 in any country within the Major Asian Countries, Major EU Countries or Major ROW Countries, then such termination as to such country shall not serve as the basis for or otherwise contribute to a claim for breach of BAXTER's obligations under Section 6.1(a) of this Agreement as to any Licensed Sub-Territory other than the Licensed Sub-Territory to which such country belongs and, notwithstanding such termination, BAXTER may satisfy its obligations under Section 6.1(a) as to such Licensed Sub-Territory by using Commercially Reasonable Efforts as set forth in Section 6.1(b). If BAXTER terminates this Agreement in accordance with this Section 12.4 in any Licensed Sub-Territory, then such termination shall not serve as the basis for or otherwise contribute to a claim for breach of BAXTER's obligations under Section 6.1(a) of this Agreement, and BAXTER shall be relieved of any obligations to use Commercially Reasonable Efforts in such Licensed Sub-Territory.

Section 12.5 <u>Termination by MERRIMACK for BAXTER Patent Challenge</u>. If BAXTER or any of its Affiliates or sublicensees challenges the validity, enforceability, patentability or scope of any claim(s) included in any Licensed Patent Rights, or supports, directly or indirectly, any such challenge (any of the foregoing, a "<u>Patent Challenge</u>"), MERRIMACK shall have the right to terminate this Agreement upon thirty (30) days' written notice to BAXTER with respect to the Licensed Patent Rights so challenged by BAXTER or any of its Affiliates or sublicensees.

Section 12.6 Effects of Termination by MERRIMACK for BAXTER Uncured Breach or BAXTER Patent Challenge, or Termination by BAXTER of Entire Agreement for Convenience. Upon termination of this Agreement in its entirety by MERRIMACK pursuant to Section 12.3 (Termination for Material Breach) or pursuant to Section 12.5 (Termination for BAXTER Patent Challenge), or termination of this Agreement in its entirety by BAXTER pursuant to Section 12.4 (Termination by BAXTER for Convenience):

- (a) All rights and licenses granted by MERRIMACK to BAXTER shall terminate and revert to MERRIMACK;
- (b) To the extent permitted by applicable Laws, BAXTER shall transfer to MERRIMACK or its designee ownership of all Regulatory Approvals, Regulatory Filings, data and the Global Dossier (but not any of BAXTER's proprietary templates or proprietary technology related to the Global Dossier, provided that BAXTER shall provide the Global Dossier in a reasonably usable form) in BAXTER's or its Affiliates' possession or control relating to the Licensed Compound and all Licensed Products (for clarity the foregoing obligation shall not apply in case of termination by BAXTER for MERRIMACK uncured material breach);
- (c) To the extent necessary for MERRIMACK to resume development or manufacturing or Commercialization of the Licensed Compound or a Licensed Product, BAXTER shall:
- (i) grant MERRIMACK or its designee a right of reference or use to any such data, Global Dossier, Regulatory Filings and Regulatory Approvals in the Licensed Territory that are not permitted to be transferred to MERRIMACK under applicable Laws, which filings or Regulatory Approvals are in BAXTER's or its Affiliates' possession or control and relate to the Licensed Compound and Licensed Products; and
- (ii) sign, and cause its Affiliates to sign, any instruments reasonably requested by MERRIMACK in order to effect the grants contemplated above in this Section 12.6(c);
- (d) BAXTER shall assign to MERRIMACK its entire right, title and interest in and to all preclinical and clinical data, safety data and all other supporting data, including pharmacology and biology data, in BAXTER's or its Affiliates' possession or control relating to, and to the extent necessary for MERRIMACK to continue the research, development or Commercialization of, the Licensed Compound and Licensed Products;

(e) At MERRIMACK's option and upon MERRIMACK's request as to any or all of the following, BAXTER (or its relevant Affiliate) shall:

(i) transfer to MERRIMACK (or its designee) the manufacturing process, documents, materials and other Know-How relating to the manufacture of the Licensed Product, to the extent the foregoing is Controlled by BAXTER, it being understood that in the case of any manufacturing process or other Know-How, BAXTER shall only be obligated to transfer to MERRIMACK what it is legally or contractually, as applicable, permitted to transfer, and shall use Commercially Reasonable Efforts to have transferred to MERRIMACK any process or other Know-How which is not under the Control of BAXTER (in all cases provided that BAXTER shall not be committed to incur any costs pursuant to the use of such process or other Know-How by or on behalf of MERRIMACK) which are used (at the time of the termination) by or on behalf of BAXTER, its Affiliates or sublicensees in the manufacture of the Licensed Compound and Licensed Products, and provide reasonable technical assistance relating to the manufacture, testing and supply of the Licensed Compound or Licensed Products as necessary for MERRIMACK to be qualified or to qualify a Third Party for the manufacturing of such Licensed Compound or Licensed Products, such assistance being limited to assistance that a manufacturer familiar with, and having experience with equipment for, manufacturing of liposomes and products containing liposomes, would require, and in any case not to exceed a total of [**] hours of working time by BAXTER's personnel over a period not to exceed [**] months;

(ii) sell to MERRIMACK (or its designee), and MERRIMACK shall purchase from BAXTER, BAXTER's then-existing inventory of the Licensed Compound and Licensed Products, at BAXTER's Manufacturing Cost plus [**] percent ([**]%);

(iii) promptly transfer to MERRIMACK or its designee ongoing clinical trials being conducted by or under authority of BAXTER as of the date of the termination notice, continue to conduct such clinical trials up to such transfer or, if requested by MERRIMACK, terminate such clinical trials in a manner conforming to applicable Laws and regulations. It is understood that BAXTER shall in no case be obligated to incur costs beyond those budgeted for the termination period in the Global Development Plan applying to such period, costs related to any change of any kind decided by MERRIMACK to the Global Development Plan, costs related to any translation or reformatting of documents or databases (it being understood that any data or databases shall be transferred on an as is basis) or costs related to converting or adapting any database or software; and

(iv) transfer to MERRIMACK any Marketing Authorization obtained on or before the date of termination and, if commercial launch of Licensed Product(s) has occurred on or before the date of termination, BAXTER shall, at the request of MERRIMACK, continue to market, promote, distribute and Commercialize the Licensed Product(s), and continue to pay amounts due to MERRIMACK pursuant to Article VIII, until the date when, on a country-by-country basis, the Marketing Authorization has been transferred to MERRIMACK or MERRIMACK's designee;

(f) BAXTER shall grant to MERRIMACK a non-exclusive, worldwide, royalty-free, irrevocable, perpetual license, with the right to grant sublicenses to any Third Party,

under the BAXTER Intellectual Property and BAXTER's interest in any Joint Patent Rights or Joint Technology, in each case solely to the extent used by BAXTER, its Affiliates or sublicensees in the research, development, manufacture or Commercialization of the Licensed Compound or Licensed Products in the Field and for the sole purpose of conducting research, development, manufacturing and/or Commercialization of the Licensed Compound or Licensed Products in the Field.

- (g) BAXTER shall assign to MERRIMACK BAXTER's and its Affiliates' entire right, title and interest in, to and under any trademark used by BAXTER, its Affiliates or sublicensees exclusively in connection with the marketing and sale of a Licensed Product, it being understood that such assignment shall not include the BAXTER name or trademark for the BAXTER company itself.
- Section 12.7 <u>Effects of Termination with Respect to One or More, but Not All, Licensed Products, Licensed Sub-Territories or Countries by BAXTER for Convenience</u>. If this Agreement is terminated pursuant to Section 12.4 with respect to one or more Licensed Products ("<u>Terminated Products</u>") or with respect to one or more Licensed Sub-Territories or to countries outside a Licensed Sub-Territory (collectively, the "<u>Terminated Territories</u>"), then:
- (a) the effects of termination set forth in Section 12.6(a), Section 12.6(e)(iii), Section 12.6(e)(iv), Section 12.6(f) and Section 12.6(g) above shall apply solely as to such Terminated Territories (in case this Agreement is terminated with respect to one or more Terminated Territories) and the effects of termination set forth in Section 12.6(a), Section 12.6(e), Section 12.6(f) and Section 12.6(g) above shall apply solely as to such Terminated Products (in case this Agreement is terminated with respect to one or more Terminated Products);
- (b) in lieu of the effects of termination set forth in Section 12.6(b) with respect to Regulatory Filings, Regulatory Approvals, data and the Global Dossier in BAXTER's or its Affiliates' possession or control relating to the Licensed Compound and all Licensed Products, BAXTER shall:
- (i) to the extent permitted by applicable Laws, transfer to MERRIMACK or its designee ownership of all such data, Global Dossier, Regulatory Filings filed in, and Regulatory Approvals received with respect to, any Terminated Products and/or Terminated Territories (or any country therein), which filings or Regulatory Approvals are in BAXTER's or its Affiliates' possession or control and relate to the Licensed Compound and Licensed Products; provided, however, if a Terminated Product received EMA Marketing Authorization based on a centralized Drug Approval Application with the EMA and BAXTER retains any country(-ies) within the EU, then BAXTER shall not be required to transfer the centralized EMA Marketing Authorization or other Regulatory Filing to MERRIMACK but shall provide MERRIMACK with a fully paid-up, non-royalty-bearing license or other authorization with the right to sublicense that enables MERRIMACK to Commercialize the applicable Terminated Product in the applicable Terminated Territory(-ies) following the termination pursuant to Section 12.4; and

- (ii) to the extent necessary for MERRIMACK to resume development or manufacturing or Commercialization of the Licensed Compound or a Licensed Product in any Terminated Territory;
- (A) grant MERRIMACK or its designee a right of reference or use to any and all such data, Global Dossier, Regulatory Filings filed in, and Regulatory Approvals received with respect to, any country or territory other than a Terminated Territory (or any country therein) and any such filings and Regulatory Approvals in any Terminated Territory (or any country therein) that are not permitted to be transferred to MERRIMACK under applicable Laws, which filings or Regulatory Approvals are in BAXTER's or its Affiliates' possession or control and relate to the Licensed Compound and Licensed Products, (for clarity BAXTER shall transfer to MERRIMACK ownership of all such Regulatory Filings and Regulatory Approvals in the event of a termination of this Agreement in its entirety (except for a termination by BAXTER for MERRIMACK uncured material breach)); and
- (B) sign, and cause its Affiliates to sign, any instruments reasonably requested by MERRIMACK in order to effect the grants contemplated above in this Section 12.7(b); and
- (c) BAXTER shall transfer to MERRIMACK, and grant MERRIMACK a right to use (consistent with the license granted to MERRIMACK under Section 12.6(f)), all preclinical and clinical data, safety data and all other supporting data, including pharmacology and biology data, in BAXTER's or its Affiliates' possession or control relating to, and to the extent necessary for MERRIMACK to continue, the research, development or Commercialization of Terminated Products, or of the Licensed Compound or Licensed Products in any Terminated Territory(-ies), as applicable.

Section 12.8 Survival.

- (a) Upon expiration or termination of this Agreement for any reason, all rights and obligations of each Party shall terminate hereunder, except as expressly set forth in Section 12.2, Section 12.6, Section 12.7 or this Section 12.8; provided, however, that nothing in this Agreement shall be construed to release either Party from any obligations or liabilities that matured prior to the effective date of expiration or termination, or which are attributable to a period prior to such expiration or termination. In addition, and notwithstanding the terms of Section 12.6(e)(iii) and Section 12.7(a), BAXTER shall remain responsible for payment to MERRIMACK of all such costs that are committed by MERRIMACK in connection with any human clinical trials conducted by MERRIMACK hereunder for a period of [**] months beyond the effective date of termination by BAXTER under Section 12.4, to the extent that the clinical trials giving rise to such costs were non-terminable as of the date of termination of this Agreement, for ethical or regulatory reasons.
- (b) Notwithstanding anything in this Agreement to the contrary, the following provisions shall expressly survive any expiration or termination of this Agreement in accordance with their terms: Article VIII (in each case, to the extent any amounts are due but unpaid as of the effective date of expiration or termination); Section 9.1; Article X; Section 12.2; Section 12.6; Section 12.7; Section 12.8; Article XIII; Article XIV; and Article XV.

Article XIII <u>Dispute Resolution</u>

Section 13.1 <u>Disputes; Executive Officers</u>. Subject to Section 2.1(f) and except for Section 2.1(e)(iii) and Section 2.1(e)(iv), in the event any dispute, claim or controversy arises out of or in relation to or in connection with this Agreement, including failure to perform under or breach of, this Agreement or any issue relating to the interpretation or application of this Agreement, the Parties shall use good faith efforts to resolve such dispute within [**] days through the JSC if the dispute is within the responsibilities of such a committee. If the Parties are unable to resolve such dispute at the JSC level or otherwise within such [**] day period or a dispute is within the responsibilities of the JSC but the JSC no longer remains in place at the time of such dispute and the Parties are unable to resolve such dispute within [**] days, the Parties shall refer such dispute to their respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute within [**] days and, if the Executive Officers are unable to resolve such dispute within such [**] day period, such dispute shall be referred to binding arbitration pursuant to Section 13.2, except that any dispute concerning inventorship arising under Section 9.1(c) shall not be subject to resolution by the Executive Officers under this Section 13.1 or by binding arbitration under Section 13.2, but shall instead be resolved by independent patent counsel as set forth in Section 9.1(c).

Section 13.2 <u>Arbitration</u>. If the Executive Officers are unable to resolve a given dispute referred to such Executive Officers pursuant to Section 13.1 within [**] days following such referral of such dispute to such Executive Officers, either Party may have the given dispute settled by binding arbitration in the manner described below:

- (a) <u>Arbitration Request</u>. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "<u>Arbitration Request</u>") to the other Party of such intention and the issues for resolution.
- (b) $\underline{Additional\ Issues}$. Within [**] days after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution.
- (c) <u>Arbitration Location</u>; <u>Language</u>. The arbitration shall be located in New York, New York, US and shall be conducted in English and a transcribed record shall be prepared in English. Documents submitted in the arbitration (the originals of which are not in English) shall be submitted together with a reasonably complete and accurate English translation.
- (d) <u>Arbitration Rules</u>. Except as expressly provided herein, the sole mechanism for resolution of any claim, dispute or controversy arising out of or in connection with or relating to this Agreement or the breach or alleged breach thereof shall be arbitration by the International Institute for Conflict Prevention & Resolution ("<u>CPR</u>") pursuant to its Arbitration Rules and Procedures (the "<u>CPR Rules</u>"). References herein to any arbitration rules or procedures mean such rules or procedures as amended from time to time, including any successor rules or procedures, and references herein to the CPR include any successor thereto. The arbitration shall be before three (3) arbitrators. Each Party shall designate one arbitrator in accordance with the "screened" appointment procedure provided in Rule 5.4 of the CPR Rules. The two Party-appointed arbitrators will select the third, who will serve as the panel's chair or

president. All three (3) arbitrators shall have experience in the pharmaceutical or biologics industry. This arbitration provision, and the arbitration itself, shall be governed by the laws of the State of New York, US and the Federal Arbitration Act, 9 U.S.C. §§1-16.

- (e) Consistent with the expedited nature of arbitration, each Party will, upon the written request of the other Party, promptly provide the other with copies of documents on which the producing Party may rely in support of or in opposition to any claim or defense. At the request of a Party, the arbitrators shall have the discretion to order examination by deposition of witnesses to the extent the arbitrator deems such additional discovery relevant and appropriate. Depositions shall be limited to a maximum of [**] per Party and shall be held within [**] days of the grant of a request. Additional depositions may be scheduled only with the permission of the arbitrators, and for good cause shown. Each deposition shall be limited to a maximum of [**] duration. All objections are reserved for the arbitration hearing except for objections based on privilege and proprietary or confidential information. The parties shall not utilize any other discovery mechanisms, including international processes and US federal statutes, to obtain additional evidence for use in the arbitration. Any dispute regarding discovery, or the relevance or scope thereof, shall be determined by the arbitrators, which determination shall be conclusive. All discovery shall be completed within [**] days following the appointment of the arbitrators. All costs and/or fees relating to the retrieval, review and production of electronic discovery shall be paid by the Party requesting such discovery.
- (f) The panel of arbitrators shall have no power to award non-monetary or equitable relief of any sort, other than injunctions. The arbitrators will have no authority to award punitive or other damages not measured by the prevailing Party's actual damages, except as may be required by statute. Except as may be required by statute, each Party expressly waives and foregoes any right to consequential, punitive, special, exemplary or similar damages or lost profits. The arbitrators shall have no power or authority, under the CPR Rules for Non-Administered Arbitration or otherwise, to relieve the Parties from their agreement hereunder to arbitrate or otherwise to amend or disregard any provision of this Agreement. The award of the arbitrators shall be final, binding and the sole and exclusive remedy to the Parties. Either Party may seek to confirm and enforce any final award entered in arbitration, in any court of competent jurisdiction. The cost of the arbitration, including the fees of the arbitrators, shall be borne by the Party the arbitrator determines has not prevailed in the arbitration.
- (g) If an arbitral award does not impose an injunction on the losing Party or contain a money damages award in excess of US\$[**], then the arbitral award shall not be appealable to a tribunal of appellate arbitrators via the CPR Arbitration Appeal Procedure but may only be challenged as permissible under the Federal Arbitration Act, 9 U.S.C. §§ 1-16. In the event that the arbitration does result in an arbitral award, which imposes an injunction or a monetary award in excess of US\$[**], such award may be appealed to a tribunal of appellate arbitrators via the CPR Arbitration Appeal Procedure, subject to any further challenges permissible under the Federal Arbitration Act, 9 U.S.C. §§ 1-16.
- (h) Except as may be required by law, neither a Party nor an arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both parties.

Article XIV Indemnification

Section 14.1 <u>Indemnification by BAXTER</u>. BAXTER shall indemnify, defend and hold harmless MERRIMACK and its Affiliates, and its and their respective directors, officers, employees and agents, from and against any and all liabilities, damages, losses, costs and expenses, including the reasonable fees of attorneys and other professional Third Parties (collectively, "<u>Losses</u>"), arising out of or resulting from any and all Third Party suits, claims, actions, proceedings or demands ("<u>Claims</u>") based upon:

- (a) the negligence, recklessness or wrongful intentional acts or omissions of BAXTER or its Affiliates and its or their respective directors, officers, employees and agents, in connection with BAXTER's performance of its obligations or exercise of its rights under this Agreement;
 - (b) any breach of any representation, warranty or covenant made by BAXTER under this Agreement;
- (c) any act or omission by BAXTER that results in a breach of any of MERRIMACK's agreements with MERRIMACK Third Party licensors, including the PharmaEngine Collaboration Agreement; or
- (d) the research, development, manufacturing and Commercialization activities that are actually conducted by or on behalf of BAXTER as to the Licensed Compound or any Licensed Product solely for the Licensed Territory, including (i) any product liability, personal injury, property damage or other damage, and (ii) infringement of any Patent Right or other intellectual property right of any Third Party (subject to the rights of BAXTER under Section 8.5(c) and excluding any such infringement Losses arising from a breach by MERRIMACK of its representations and warranties set forth in Section 11.2), in each case resulting from any of the foregoing activities described in this Section 14.1(d).

Section 14.2 <u>Indemnification by MERRIMACK</u>. MERRIMACK shall indemnify, defend and hold harmless BAXTER and its Affiliates, and its or their respective directors, officers, employees and agents, from and against any and all Losses, arising out of or resulting from any and all Third Party Claims based upon:

- (a) the negligence, recklessness or wrongful intentional acts or omissions of MERRIMACK or its Affiliates or its or their respective directors, officers, employees and agents, in connection with MERRIMACK's performance of its obligations or exercise of its rights under this Agreement;
 - (b) any breach of any representation, warranty or covenant made by MERRIMACK under this Agreement;
 - (c) any breach of the PharmaEngine Collaboration Agreement except if such breach was caused by any action or omission of BAXTER; and

(d) the research, development, manufacturing and Commercialization activities that are actually conducted by or on behalf of MERRIMACK as to the Licensed Compound or any Licensed Product solely for the MERRIMACK Territory, including (i) any product liability, personal injury, property damage or other damage, and (ii) infringement of any Patent Right or other intellectual property right of any Third Party arising from a breach by MERRIMACK of its representations and warranties set forth in Section 11.2, in each case resulting from any of the foregoing activities described in this Section 14.2(d).

Section 14.3 Procedure.

- (a) A Person entitled to indemnification under this Article XIV (an "<u>Indemnified Party</u>") shall give prompt written notification to the Person from whom indemnification is sought (the "<u>Indemnifying Party</u>") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third-Party claim as provided in this Section 14.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice).
- (b) Within [**] days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party.
- (c) If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all costs and expenses, including reasonable attorney's fees, incurred by the Indemnified Party in defending itself within [**] days after receipt of any invoice therefor from the Indemnified Party.
- (d) The Party not controlling such defense may participate therein at its own expense, provided that if the Indemnifying Party assumes control of such defense and the Indemnified Party in good faith concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party in connection with its participation in the defense action.
- (e) The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto.
- (f) The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect

thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto, that imposes any liability or obligation on the Indemnified Party or that acknowledges fault by the Indemnified Party without the prior written consent of the Indemnified Party.

Section 14.4 <u>Insurance</u>. Each Party shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations and liabilities hereunder and which are consistent with normal business practices of comparable companies with respect to similar obligations and liabilities, at all times during which the Licensed Compound and Licensed Products are clinically tested or commercially distributed or sold by or on behalf of such Party or its Affiliates. It is understood that such insurance shall not be construed to create any limit of either Party's obligations or liabilities with respect to its indemnification obligations hereunder. Each Party shall provide the other, upon request, with evidence of such insurance. Each Party shall have the right to meet its insurance obligations under this Section 14.4 through a self-insurance program that is consistent with the normal business practices of comparable companies in lieu of procuring and maintaining Third Party insurance.

Section 14.5 <u>Limitation of Liability</u>. EXCEPT TO THE EXTENT SUCH PARTY MAY BE REQUIRED TO INDEMNIFY THE OTHER PARTY UNDER THIS ARTICLE XIV WITH RESPECT TO THIRD PARTY CLAIMS AND WITH RESPECT TO BREACHES OF ARTICLE X, NEITHER PARTY NOR ITS RESPECTIVE AFFILIATES OR SUBLICENSEES SHALL BE LIABLE FOR ANY (AND HEREBY DISCLAIM ALL) SPECIAL, EXEMPLARY, CONSEQUENTIAL, PUNITIVE OR OTHER INDIRECT DAMAGES, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT LIABILITY OR OTHER LEGAL THEORY.

Article XV Miscellaneous Provisions

Section 15.1 <u>Governing Law.</u> Except for matters of intellectual property law, which shall be determined in accordance with the national intellectual property laws relevant to the intellectual property in question, this Agreement, and any disputes between the Parties relating to the subject matter of this Agreement, shall be construed and the respective rights of the Parties hereto determined according to the substantive laws of the State of New York, US, excluding (a) its conflicts of laws principles, (b) the United Nations Conventions on Contracts for the International Sale of Goods, (c) the 1974 Convention on the Limitation Period in the International Sale of Goods (the "1974 Convention"), and (d) the Protocol amending the 1974 Convention, done at Vienna April 11, 1980.

Section 15.2 <u>Assignment</u>. Neither MERRIMACK nor BAXTER may assign this Agreement in whole or in part without the prior written consent of the other, except to an Affiliate or in connection with the merger, sale, divestiture, spin-off or transfer of all or substantially all of the stock, assets or business of MERRIMACK, on the one hand, or BAXTER, on the other, to which the subject matter of this Agreement pertains. The assigning Party shall remain primarily liable for the performance of this Agreement notwithstanding any such assignment of this Agreement, provided that following the assignment of this Agreement by BII, BHC and BHSA to a new entity to be formed by BAXTER ("New Baxter") pursuant to the

planned spin-off transaction that was publicly announced prior to the Effective Date, and New Baxter's and its ultimate parent entity's assumption of BAXTER's obligations hereunder in connection therewith, BII, BHC and BHSA shall no longer be liable for any performance under this Agreement.

Section 15.3 Entire Agreement; Amendments. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all previous arrangements with respect to the subject matter hereof, whether written or oral, including the Confidentiality Agreement. Any amendment or modification to this Agreement shall be made in writing signed by both Parties.

Section 15.4 <u>Notices</u>. Any notice required or provided for by the terms of this Agreement shall be in writing and shall be sufficient if (a) delivered personally or (b) sent by registered or certified mail, return receipt requested, reputable overnight business courier, email or fax (each with return confirmation) in each case properly addressed to a Party as set forth below. The effective date of notice shall be the actual date of receipt by the Party receiving the same.

Notices to MERRIMACK shall be addressed to:

Merrimack Pharmaceuticals, Inc. One Kendall Square, Suite B7201 Cambridge, MA 02139 U.S.A.

Telephone: (617) 441-1000 Facsimile: (617) 491-1386 Attention: Chief Executive Officer

with a copy to:

Merrimack Pharmaceuticals, Inc. One Kendall Square, Suite B7201 Cambridge, MA 02139 U.S.A. Telephone: (617) 441-1000

Telephone: (617) 441-1000 Facsimile: (617) 491-1386 Attention: Legal Department

with a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street
Boston, Massachusetts 02109
U.S.A.

Telephone: (617) 526-6238 Facsimile: (617) 526-5000

Email: Steven.Barrett@wilmerhale.com Attention: Steven D. Barrett, Esq.

Notices to BAXTER shall be addressed to:

Baxter Healthcare SA Postfach 8010 Zürich, Switzerland Telephone: +41 44 878 60 00 Facsimile: +41 44 878 63 50 Attention: Legal Department

with a copy to:

Baxter Healthcare Corporation One Baxter Parkway Deerfield, Illinois 60015 U.S.A.

Telephone: (224) 948-3440 Facsimile: (224) 948-2590 Email: david_scharf@baxter.com Attention: General Counsel

and a copy to:

McDermott Will & Emery LLP 227 W. Monroe Avenue Chicago, IL 60601 U.S.A.

Telephone: (312) 984-2157 Facsimile: (312) 984-7700 Email: kwerling@mwe.com Attention: Kristian A. Werling

Any Party may change its notification address by giving notice to the other Party in the manner herein provided. For clarity, the additional copy will be addressed for convenience only and the notification shall be deemed to have been validly delivered when addressed to the main addressee.

Section 15.5 Exports. The Parties acknowledge that the export of technical data, materials or products is subject to the exporting Party receiving any necessary export licenses and that the Parties cannot be responsible for any delays attributable to export controls that are beyond the reasonable control of either Party. BAXTER and MERRIMACK agree not to export or reexport, directly or indirectly, the Licensed Compound or any Licensed Product (or any associated products, information, items, articles, computer software, media, technical data, the direct product of such data, samples or equipment received or generated under this Agreement) in violation of any US export laws or other Laws or regulations that may be applicable. BAXTER and MERRIMACK agree to obtain similar covenants from their Affiliates, sublicensees and contractors with respect to the subject matter of this Section 15.5.

Section 15.6 Force Majeure. Either Party shall be excused from the performance of its obligations under this Agreement, and no failure or omission by a Party in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the control of such Party, (including the following: acts of God; acts or omissions of any government; any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; labor disputes, epidemic, failure or default of public utilities or common carriers, fire; storm; flood; earthquake; accident; war; rebellion; terrorism; insurrection; riot; and invasion) and such excuse shall be continued so long as the condition constituting force majeure continues, provided that such failure or omission resulting from one of the above causes is cured as soon as is practicable after the end of the occurrence of one or more of the above-mentioned causes. The Party claiming such force majeure shall notify the other Party with notice of the force majeure event as soon as practicable, but in no event longer than five (5) Business Days after its occurrence, which notice shall reasonably identify the affected obligations under this Agreement and the extent to which performance thereof will be affected. In such event, the Parties shall meet and/or discuss promptly to determine an equitable solution to minimize and if reasonably feasible, overcome, the effects of any such event.

Section 15.7 <u>Performance by Affiliates and Sublicensees; Joint and Several Liability.</u> To the extent that this Agreement imposes obligations on Affiliates or sublicensees of a Party, such Party agrees to cause such Party's Affiliates and sublicensees to perform such obligations. Without limiting the foregoing, BII, BHC and BHSA shall be jointly and severally liable for all of BAXTER's obligations under this Agreement.

Section 15.8 <u>Independent Contractors</u>. It is understood and agreed that the relationship between the Parties hereunder is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either MERRIMACK or BAXTER to act for, bind or commit the other in any way. The Alliance Managers shall remain employees of BAXTER or MERRIMACK, as the case may be.

Section 15.9 <u>Construction</u>. Each Party agrees that this Agreement shall be interpreted without regard to any presumption or rule requiring construction against the Party causing this Agreement to be drafted.

Section 15.10 Interpretation. Any reference in this Agreement to an Article, Section, subsection, paragraph, clause, Schedule or Exhibit shall be deemed to be a reference to any Article, Section, subsection, paragraph, clause, Schedule or Exhibit, of or to, as the case may be, this Agreement. Except where the context clearly otherwise requires, (a) wherever used, the use of any gender will be applicable to all genders, (b) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (c) any reference to any laws refers to such laws as from time to time enacted, repealed or amended, (d) the words "herein", "hereof" and hereunder", and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, (e) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation" or words of similar import, (f) the word "day" means a calendar day, the word

"month" means a calendar month and the word "year" means a calendar year, (g) the word "quarterly" refers to calendar quarters (e.g., January 1 to March 31, April 1 to June 30, July 1 to September 30 or October 1 to December 31) and (h) each accounting term used herein that is not specifically defined herein shall have the meaning given to it under applicable IFRS, to the extent consistent with its usage and the other definitions in this Agreement.

Section 15.11 <u>Headings</u>. The captions or headings of the Sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.

Section 15.12 English Language. This Agreement was prepared and is established in the English language, any translation thereof shall be deemed for convenience only and shall never prevail against the original English version. All reports, notices and communications to be exchanged under this Agreement shall be in the English language; provided, however, that, notwithstanding anything herein to the contrary, neither Party shall be under any obligation to translate into English any document originally established and existing in another language, for the sole purpose of communicating such document to the other Party, it being agreed that such documents will be provided on an as is basis.

Section 15.13 No Implied Waivers; Rights Cumulative. No failure on the part of MERRIMACK or BAXTER to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

Section 15.14 <u>Severability</u>. If, under applicable Laws, any provision of this Agreement is held to be invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (such invalid or unenforceable provision, a "<u>Severed Clause</u>"), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use reasonable efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the objectives contemplated by the Parties when entering into this Agreement and the general balance of the respective interests of the Parties as initially intended under this Agreement.

Section 15.15 Execution in Counterparts. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

MERRIMACK PHARMACEUTICALS, INC.

By: /s/ Robert J. Mulroy

Name: Robert J. Mulroy Title: President + CEO

BAXTER INTERNATIONAL INC.

By: /s/ Robert J. Hombach

Name: Robert J. Hombach

Title: CVP, Chief Financial Officer

BAXTER HEALTHCARE CORPORATION

By: /s/ Robert J. Hombach

Name: Robert J. Hombach

Title: CVP, Chief Financial Officer

BAXTER HEALTHCARE SA

By: /s/ Stuart Edgley

Name: Stuart Edgley Title: VP Finance EMEA

Exhibit A

Initial Global Development Plan

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of two pages were omitted. [**].

The initial budget for the Second Indication will be \$98,800,000.

[**].

A-1

Exhibit B

Licensed Patent Rights

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. A total of one page was omitted. [**]

Exhibit C

MM-398

[**]

C-1

Exhibit D

Terms of MERRIMACK Supply Agreement

The following is a summary of certain material terms relating to the manufacture and supply of Drug Product from MERRIMACK to BAXTER that will be contained in a definitive MERRIMACK Supply Agreement. In accordance with Section 3.5 of the Agreement, the Parties shall enter into the MERRIMACK Supply Agreement on or before a date to be established by the JSC, but in no event later than [**] days after the Effective Date. The negotiated terms of the MERRIMACK Supply Agreement shall be consistent with the Agreement and the following binding terms, provided that neither Party shall have any obligation to perform such terms until the Parties have entered into a definitive MERRIMACK Supply Agreement:

Description

Topic

1	Objectives and Scope	MERRIMACK and BAXTER shall enter into an exclusive commercial supply agreement whereby MERRIMACK will manufacture and supply Drug Product to BAXTER for BAXTER to use, market, sell, offer for sale and have sold in the Licensed Territory.
2	Drug Product	Bulk drug product containing the Licensed Compound, but excluding any final packaging, finishing and vialing.
3	Territory	Licensed Territory
4	Term	The MERRIMACK Supply Agreement will have an initial term of five (5) years and will automatically renew for additional two (2) year periods unless notice not to renew is delivered by BAXTER at least twelve (12) months prior to the end of the then current term.
		Notwithstanding the foregoing, at any time after [**], MERRIMACK may elect to terminate the MERRIMACK Supply Agreement upon twenty-four (24) months' advance written notice to BAXTER.
		Upon notice of termination or, in the case of expiration, no less than [**] months prior to expiration or termination, of the MERRIMACK Supply Agreement as described above, MERRIMACK would, if requested by BAXTER, commence providing BAXTER with a technology transfer of MERRIMACK's manufacturing process such that the technology transfer is completed prior to termination or expiration in accordance with terms and conditions substantially the same as set forth in Section 3.8 of the Agreement.
5	Forecasts	BAXTER shall provide MERRIMACK with forecasts (partial binding/non-binding). The timeframe for such forecasts shall be aligned with relevant CMO, raw material procurement and capacity planning timelines. BAXTER shall include in its forecast any requirement for safety stock and BAXTER shall be responsible for all costs associated with such safety stock.

6	Supply Price	BAXTER shall purchase Drug Product from MERRIMACK at a supply price equal to [**] percent ([**]%) of MERRIMACK's Manufacturing Costs (as defined in Section 1.50 of the Agreement). Solely for purposes of reference, the current Manufacturing Costs for Drug Product are estimated at \$[**] per gram, yielding a current supply price of \$[**] per gram.
		Fill and finish, freight, insurance and other subsequent supply chain expenses are not included in the supply price.
		The supply price shall be adjusted on an annual basis to reflect changes in MERRIMACK's Manufacturing Costs.
7	Delivery	EXW (ICC Incoterms 2010) MERRIMACK's manufacturing facility.
8	Specifications, Certificate of Analysis	In conjunction with each delivery, MERRIMACK shall provide a signed Certificate of Analysis certifying that such shipment was tested and meets the specifications.
10	Payment	MERRIMACK shall issue invoices upon delivery of Drug Product to BAXTER. BAXTER shall pay such invoices within [**] days.
11	Supply Failure	The MERRIMACK Supply Agreement shall include appropriate technology transfer provisions sufficient to enable BAXTER to manufacture or have manufactured Drug Product in the event of a supply failure (which shall be defined as the failure to supply at least [**] percent ([**]%) of BAXTER's forecasts for a period of [**] days). If a technology transfer is commenced following a failure to supply resulting from a breach by MERRIMACK of the MERRIMACK Supply Agreement, then such technology transfer shall be promptly provided by MERRIMACK [**] to BAXTER.
12	Representations, Warranties / Indemnification / Limitations of Liability	The MERRIMACK Supply Agreement shall contain customary representations and warranties relating to the manufacture and supply of Drug Product, including each Party's obligation to comply with all applicable Laws. In addition, the MERRIMACK Supply Agreement shall include appropriate indemnification provisions and limitations of liability. Such representations, warranties and indemnification shall be consistent with the liability allocation provisions of the Agreement (i.e., shall be tailored to address manufacturing defect-caused liability) and such limitations of liability shall be consistent with limitations of liability that are typical for commercial contract manufacturing contracts.
13	Recalls	Section 4.3 of the Agreement shall govern the Parties' obligations with respect to recalls, withdrawals or field corrections; provided, however, that the MERRIMACK Supply Agreement shall provide for no-cost replacement of Drug Product and allocation of recall expenses if the recall, withdrawal or field correction was due to the failure of the Drug Product to comply with specifications or cGMP (unless such non-compliance was caused by BAXTER).
14	Non-Conforming Supply	The MERRIMACK Supply Agreement shall contain timelines for receipt, testing and acceptance of Drug Product by BAXTER, as well as terms for the replacement of non-conforming Drug Product if necessary.

CONFIDENTIAL

EXECUTION VERSION

15 Supply Constraints

Approvals and

Inspections

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The MERRIMACK Supply Agreement will include provisions for the management of a constrained supply of Drug Product such that MERRIMACK and BAXTER share available supply so that each Party's allocation is proportionate to their respective [**]-month rolling forecast submitted to the fill-finish supplier. For example, if A is MERRIMACK's [**]-month rolling forecast, B is BAXTER's [**]-month rolling forecast and T is the total supply available, then if a supply constraint occurs, MERRIMACK's share of available supply shall be (A/(A+B))*T and BAXTER's share of available supply shall be (B/(A+B))*T.

MERRIMACK shall use Commercially Reasonable Efforts to ensure that MERRIMACK's Drug Product manufacturing facility, the facility of MERRIMACK's current irinotecan API supplier and the facility of MERRIMACK's current fill/finish CMO comply with requirements of EMA and MHLW prior to launch in the first Major EU Territory, Japan and in any other Major Asian Countries and Major ROW Countries and that any other Drug Product manufacturing facility, irinotecan API supplier or fill/finish CMO controlled by or under contract with MERRIMACK at any time after the Effective Date comply with such requirements in a timely manner, as applicable (including the provision of necessary development and process information required to support Regulatory Filings). If there is a change in MERRIMACK's irinotecan API supplier at any time, MERIMACK will provide notice of such change to BAXTER in advance and such irinotecan supplier will comply with applicable EMA and MHLW requirements. BAXTER shall be responsible for all reasonable costs related to complying with EMA or MHLW requirements.

For the avoidance of doubt, MERRIMACK shall use Commercially Reasonable Efforts to ensure that MERRIMACK's Drug Product manufacturing facility, the facility of MERRIMACK's current irinotecan API supplier and the facility of MERRIMACK's current fill/finish CMO are "inspection-ready" by [**] for an EMA inspection. MERRIMACK shall cooperate in any such inspections. However, MERRIMACK shall not be responsible for any regulatory submissions in the Licensed Territory, including any submissions that would trigger inspection by a Regulatory Authority.

BAXTER shall reasonably cooperate with and provide assistance to MERRIMACK with respect to the activities to be undertaken in the preceding two paragraphs, at BAXTER's cost.

17	Process Changes	MERRIMACK shall give BAXTER reasonable advance notice and opportunity to approve (which approval shall not be unreasonably withheld) any material changes that are being considered with respect to the manufacturing process for Drug Product that may reasonably be expected to impact the manufacture of the Drug Product or the Commercialization of the Licensed Product in the Licensed Territory.
18	Confidentiality	Article X of the Agreement shall govern the Parties' obligations with respect to confidentiality.
19	Dispute Resolution	Article XIII of the Agreement shall govern the Parties' rights and obligations with respect to the resolution of disputes.
20	Mutuality of Terms	If BAXTER elects to establish its own commercial scale manufacturing capabilities for Drug Product, MERRIMACK and BAXTER shall enter into an agreement pursuant to which BAXTER shall, at MERRIMACK's option, provide Drug Product to MERRIMACK under substantially the same terms as MERRIMACK provides to BAXTER.
		BAXTER shall have the option to (A) perform, by itself or through one or more CMOs, vialing of Drug Product or (B)

CONFIDENTIAL

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Fill and Finish

have MERRIMACK, on BAXTER'S behalf, manage the vialing of Drug Product at MERRIMACK's current fill/finish CMO or such other CMO as the Parties mutually agree upon. BAXTER shall provide appropriate notice of BAXTER's intention to elect either (A) or (B) above to allow MERRIMACK to plan resources appropriately and align on timing with the CMO.

EXECUTION VERSION

Regardless of whether BAXTER elects (A) or (B) above, BAXTER shall be responsible for vialing and all downstream supply chain activities and all costs related to vialing, including freight, insurance, materials and vendor management. Third Party costs will be passed through to BAXTER [**] and MERRIMACK personnel will be billed at the [**] FTE Rate.

BAXTER shall be responsible for releasing vialed Licensed Product for use in the Licensed Territory. MERRIMACK will perform analytical methods transfer in a timely manner to BAXTER or BAXTER'S CMO in order to enable BAXTER to release Licensed Product in the Licensed Territory. MERRIMACK shall invoice BAXTER for the reasonable costs of transferring the analytical methods at the [**] FTE Rate.

Exhibit E

BAXTER Restrictions

In partial consideration of the rights and licenses granted to BAXTER under this Agreement, BAXTER hereby agrees that, during the three (3) year period after the Effective Date, unless BAXTER shall have been specifically invited in writing by MERRIMACK, neither BAXTER nor any of its controlled affiliates (as such term is defined under the Securities Exchange Act of 1934, as amended (the "1934 Act")) will in any manner, directly or indirectly:

- (a) effect or seek, offer or propose (whether publicly or otherwise) to effect, or cause or participate in or in any way advise, assist or encourage any other Person to effect or seek, offer or propose (whether publicly or otherwise) to effect or participate in, (i) any acquisition of any securities (or beneficial ownership thereof) or a substantial portion of the assets of MERRIMACK, or any rights to acquire any such securities (including derivate securities representing the right to vote or economic benefit of any such securities) or assets; (ii) any tender or exchange offer, merger or other business combination involving MERRIMACK; (iii) any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to MERRIMACK; or (iv) any "solicitation" of "proxies" (as such terms are used in the proxy rules of the SEC) or consents to vote any voting securities of MERRIMACK;
 - (b) form, join or in any way participate in a "group" (as defined under the 1934 Act) with respect to any securities of MERRIMACK;
- (c) otherwise act, alone or in concert with others, to seek to control or influence the management, Board of Directors or policies of MERRIMACK;
- (d) take any action that might force MERRIMACK to make a public announcement regarding any of the types of matters set forth in (a) above; or
 - (e) enter into any discussions or arrangements with any Third Party with respect to any of the foregoing.

BAXTER also agrees during such period not to request MERRIMACK (or its directors, officers, employees or agents), directly or indirectly, to amend or waive any provision of this paragraph (including this sentence). Notwithstanding anything to the contrary contained in this Agreement, (A) if, at any time a Third Party (w) commences a tender offer for at least fifty percent (50%) of the outstanding capital stock of MERRIMACK, (x) commences a proxy contest with respect to the election of any directors of MERRIMACK, or (y) enters into an agreement with MERRIMACK contemplating the acquisition (by way of merger, tender offer or otherwise) of at least fifty percent (50%) of the outstanding capital stock of MERRIMACK or all or substantially all of its assets, then, in any of the foregoing cases, the restrictions set forth in this paragraph shall terminate and cease to be of any further force or effect, (B) if MERRIMACK publicly announces its plans to complete a transaction for at least fifty percent (50%) of the outstanding capital stock of MERRIMACK, the restrictions set forth in this paragraph shall terminate and cease to be of any further force or effect, (C) the restrictions set forth in this paragraph shall not apply to any acquisition of assets or securities of MERRIMACK, as debtor, in a transaction subject to the approval of the US Bankruptcy Court pursuant to proceedings under the

Bankruptcy Code and (D) the restrictions set forth in this Exhibit E shall not apply to (I) any investment in any securities of MERRIMACK by or on behalf of any pension or employee benefit plan or trust, or (II) securities of MERRIMACK held by a Person acquired by BAXTER on the date such Person first entered into an agreement to be acquired by BAXTER. BAXTER represents and warrants that as of the Effective Date, neither BAXTER nor any of its controlled affiliates owns, of record or beneficially, any voting securities of MERRIMACK, or any securities convertible into or exercisable for any such voting securities.

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

FIRST AMENDMENT TO ASSIGNMENT, SUBLICENSE AND COLLABORATION AGREEMENT

This First Amendment to Assignment, Sublicense and Collaboration Agreement (this "<u>Amendment</u>"), dated as of September 22, 2014 (the "<u>Amendment Effective Date</u>"), is by and between Merrimack Pharmaceuticals (Bermuda) Ltd. ("<u>MERRIMACK</u>") and PharmaEngine, Inc. ("<u>PEI</u>").

WHEREAS, MERRIMACK and PEI are parties to an Assignment, Sublicense and Collaboration Agreement, dated as of May 5, 2011 (the "Agreement"); and

WHEREAS, MERRIMACK and PEI desire to amend the Agreement as provided herein.

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the Parties, intending to be legally bound, hereby agree as follows:

- 1. <u>Definitions</u>. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.
- 2. Amendments to Agreement Terms.
- (a) Section 1.79 of the Agreement is hereby amended and restated in its entirety to read as follows:

"Section 1.79 "Sublicense Revenue". Sublicense Revenue means cash or cash equivalent consideration received by MERRIMACK or an Affiliate of MERRIMACK from a Third Party as consideration for a license or sublicense of rights to Develop and/or Commercialize the Licensed Compound or the Licensed Product in the MERRIMACK Territory; provided, however, that, if MERRIMACK or an Affiliate of MERRIMACK receives compensation in the form of development, regulatory or approval milestone payments that are not otherwise excluded below and that are based on the same development, regulatory or approval milestones on which the development, regulatory or approval milestone payments payable by MERRIMACK to PEI under this Agreement are based, Sublicense Revenue will include only the portion of such milestone payments in excess of the milestone payments payable by MERRIMACK to PEI under this Agreement based on the same milestones. In addition, Sublicense Revenue shall specifically exclude:

- (a) upfront fees payable upon the grant of the license or sublicense;
- (b) payments or reimbursements for the cost of MERRIMACK's or its Affiliates' research and development efforts for the Licensed Compound or the Licensed Product to be performed after the effective date of the applicable license or sublicense, accounted for at reasonable and customary FTE rates (any excess over a reasonable and customary FTE rate shall be included in Sublicense Revenue) or in the form of external costs billed through on a pass-through basis with no markup;

- (c) research and development milestone payments up to an aggregate total of \$150.0 million;
- (d) royalties and sales milestone payments (or, in the case of a profit sharing deal structure, shares of net profits);
- (e) payments to MERRIMACK or its Affiliates of the purchase price of equity securities to the extent not exceeding the fair market value of such securities:
- (f) loan proceeds paid to MERRIMACK or its Affiliates by a licensee or sublicensee in arm's length debt financing on non-preferential commercial terms that are, other than amounts forgiven upon or following termination of the applicable licensee's or sublicensee's rights, subject to repayment by MERRIMACK or its Affiliates (any amount of such a loan forgiven by the lender for any reason other than termination of the applicable licensee's or sublicensee's rights shall be included in Sublicense Revenue); and
- (g) payment for material supplied by MERRIMACK or its Affiliates, including a reasonable and customary margin on such material (any excess over a reasonable and customary margin is included in Sublicense Revenue).

If MERRIMACK or an Affiliate of MERRIMACK receives consideration from a Third Party for a license or sublicense (x) of rights to Develop and/or Commercialize the Licensed Compound or the Licensed Product in both the MERRIMACK Territory, and territories outside the MERRIMACK Territory, and/or (y) of rights to Develop and/or Commercialize the Licensed Compound or the Licensed Product in the MERRIMACK Territory and to Develop and/or Commercialize other compound(s) or product(s), then (1) such consideration (to the extent not excluded from Sublicense Revenue as set forth above) shall be reasonably allocated by MERRIMACK between, as applicable, the MERRIMACK Territory and such other territories and/or the Licensed Compound and the Licensed Product and such other compound(s) and product(s), and the portion allocated to the Licensed Compound and the Licensed Product in the MERRIMACK Territory will be the proposed Sublicense Revenue for such Third Party agreement; and (2) MERRIMACK shall promptly notify PEI of, and provide PEI with a copy of, each such agreement with a Third Party, along with an explanation of any allocation with respect to the consideration under such Third Party agreement in accordance with the immediately preceding sentence. If PEI does not agree with MERRIMACK's allocation of such consideration, PEI shall provide MERRIMACK with written notice of PEI's disagreement within [**] days after MERRIMACK notifies PEI of such allocation and PEI and MERRIMACK will negotiate and endeavor to agree in good faith on an allocation within [**] days after the date MERRIMACK receives such written notice. If the Parties agree within such [**] day period, the Parties will use such agreed-upon allocation to determine the Sublicense Revenue for use in the calculation set forth in Section 9.5. If despite good faith efforts the Parties are unable to agree upon such allocation within such [**] day period, then either Party may request that the allocation be determined by arbitration in accordance with Section 14.2, and, if the arbitrators determine that a different allocation is appropriate, the Parties will use the allocation determined by the arbitrators to determine the Sublicense Revenue for use in calculation set forth in Section 9.5.

For avoidance of doubt, (i) the upfront payment required under Section 9.1 is not considered a development, regulatory or approval milestone payment for purposes of this Section 1.79 and no milestone or other payment received by MERRIMACK or an Affiliate from a Third Party will be reduced by such upfront payment required under Section 9.1 for purposes of calculating Sublicense Revenue; and (ii) if MERRIMACK or its Affiliate receives any development, regulatory or approval milestone payments that are not otherwise excluded from Sublicense Revenue as set forth above and that are based on different development, regulatory or approval milestones than the milestones on which the development, regulatory or approval milestone payments payable by MERRIMACK to PEI under this Agreement are based, the full amount of such milestone payments will be included in Sublicense Revenue."

(b) The milestone event contained in Section 9.2(a)(ii) of the Agreement is hereby amended and restated its entirety to read as follows:

"First acceptance by the FDA of the filing of the first NDA for the Licensed Compound in the USA; <u>provided that</u>, if such first acceptance has not occurred by April 1, 2015, MERRIMACK shall make the payment required for this milestone no later than April 30, 2015"

- (c) Section 9.2(a) of the Agreement is hereby further amended to add an additional \$7.0 million milestone payment which is triggered by execution by MERRIMACK or any MERRIMACK Affiliate of a license or sublicense of rights to Develop and/or Commercialize the Licensed Compound or the Licensed Product in the MERRIMACK Territory.
 - (d) Section 9.5 of the Agreement is hereby amended and restated in its entirety to read as follows:

"Section 9.5 Sublicense Revenue. MERRIMACK shall pay to PEI a portion of all Sublicense Revenue as follows:

Sublicense Timeframe	Portion of Sublicense Revenue to be paid to PEI	
Sublicense agreement executed prior to [**].	[**]%	
Sublicense agreement executed on or after [**].	[**]%"	

- 3. <u>Effectiveness</u>. Notwithstanding anything to the contrary in this Amendment, the terms of this Amendment will not take effect unless and until MERRIMACK or any Affiliate of MERRIMACK enters into a license or sublicense of rights to Develop and/or Commercialize the Licensed Compound or the Licensed Product in the MERRIMACK Territory.
- 4. <u>Miscellaneous</u>. The Parties hereby confirm and agree that, except as expressly amended hereby, the provisions of the Agreement remain unchanged and in full force and effect, and the Agreement remains a binding obligation of the Parties. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures and signatures transmitted via PDF shall be treated as original signatures. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting the Agreement.

[Remainder of This Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

MERRIMACK PHARMACEUTICALS (BERMUDA) LTD. PHARMAENGINE, INC.

By:/s/ Edward J. StewartBy:/s/ Grace YehName:Edward J. StewartName:Grace YehTitle:PresidentTitle:President + CEO

THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "Amendment") is dated as of November 6, 2014 (the "Third Amendment Date"), with effect as of and from September 30, 2014, and is entered into by between MERRIMACK PHARMACEUTICALS, INC., a Delaware corporation, and each of its Subsidiaries that from time to time becomes a party hereto (hereinafter collectively referred to as "Borrower"), and HERCULES TECHNOLOGY GROWTH CAPITAL, INC., a Maryland corporation ("Lender").

RECITALS

- **A.** Borrower and Lender entered into that certain Loan and Security Agreement, dated as of November 8, 2012, as amended by that certain Amendment, Consent and Waiver, dated as of July 10, 2013, and that certain Second Amendment to Loan and Security Agreement dated as of June 25, 2014, and as amended, modified or restated from time to time (the "*Loan Agreement*"). Capitalized terms used herein without definition shall have the same meanings given them in the Loan Agreement.
- B. Borrower and Lender have agreed that, effective as of September 30, 2014, the regularly scheduled principal payments under the Loan Agreement shall commence on February 1, 2015, on the terms stated in the Loan Agreement.
 - C. Borrower and Lender have agreed to amend the Loan Agreement upon the terms and conditions more fully set forth herein.

AGREEMENT

NOW, THEREFORE, the parties hereto agree as follows:

1. AMENDMENT.

- **1.1** Section 2.1(d) of the Agreement is amended to read as follows:
- (d) Payment. Borrower will pay interest on each Term Advance in arrears on the first business day of each month beginning on the month after the Advance Date and ending on January 1, 2015 (the "Interest Only Period"). Borrower shall repay the aggregate Term Loan principal balance that is outstanding on February 1, 2015 in equal monthly installments of principal and interest (based on a 30 month amortization schedule) beginning February 1, 2015 and continuing on the first business day of each month thereafter. The entire Term Loan principal balance and all accrued but unpaid interest hereunder, shall be due and payable on the Maturity Date. Borrower shall make all payments under this Agreement without setoff, recoupment or deduction and regardless of any counterclaim or defense. Lender will initiate debit entries to the Borrower's account as authorized on the ACH Authorization on each payment date of all periodic obligations payable to Lender under each Term Note or Term Advance.

2. BORROWER'S REPRESENTATIONS AND WARRANTIES. Borrower represents and warrants that:

(a) Immediately upon giving effect to this Amendment (i) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (ii) no Event of Default has occurred and is continuing with respect to which Borrower has not been notified in writing by Lender;

- **(b)** The certificate of incorporation, bylaws and other organizational documents of Borrower previously delivered to Lender remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;
- (c) The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized by all necessary corporate action on the part of Borrower;
 - **3. EFFECTIVENESS.** This Amendment shall become effective as of September 30, 2014 upon the satisfaction of all the following conditions precedent:
 - 3.1 Amendment. Borrower and Lender shall have duly executed and delivered to Lender this Amendment.
- **3.2 No Default.** As of the Third Amendment Date, no fact or condition exists that would (or would, with the passage of time, the giving of notice, or both) constitute an Event of Default.
- **3.3 Expenses.** Borrower shall have paid to Lender with respect to this Amendment an amount equal to the reasonable attorneys' fees that Lender incurred in connection with this Amendment.
- **4. COUNTERPARTS.** This Amendment may be signed in any number of counterparts, with the same effect as if the signatures to each such counterpart were upon a single instrument. All counterparts shall be deemed an original of this Amendment.
- **5. INTEGRATION.** This Amendment contains the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements, and no extrinsic evidence may be introduced in any judicial or arbitration proceeding, if any, involving this Amendment.

[signature page follows]

IN WITNESS WHEREOF, the parties have duly authorized and caused this Amendment to be executed as of the date first written above.

BORROWER:

MERRIMACK PHARMACEUTICALS, INC.

By: /s/ Jeffrey A. Munsie
Name: Jeffrey A. Munsie

Title: General Counsel

LENDER:

HERCULES TECHNOLOGY GROWTH CAPITAL, INC.

By: /s/ Ben Bang
Name: Ben Bang

Title: Associate General Counsel

CERTIFICATIONS

I, Robert J. Mulroy, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Merrimack 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.

Date: November 10, 2014

/s/ Robert J. Mulroy

Robert J. Mulroy President and Chief Executive Officer (Principal Executive Officer)

CERTIFICATIONS

I, William A. Sullivan, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Merrimack 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.

Date: November 10, 2014

/s/ William A. Sullivan

William A. Sullivan Chief Financial Officer and Treasurer (Principal Financial Officer)

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 Merrimack Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert J. Mulroy, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (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.

Date: November 10, 2014 /s/ Robert J. Mulroy

Robert J. Mulroy President and Chief Executive Officer (Principal Executive Officer)

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 Merrimack Pharmaceuticals, Inc. (the "Company") for the period ended September 30, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, William A. Sullivan, Chief Financial Officer and Treasurer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (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.

Date: November 10, 2014

/s/ William A. Sullivan

William A. Sullivan Chief Financial Officer and Treasurer (Principal Financial Officer)