

MERRIMACK PHARMACEUTICALS INC  
Form 10-Q  
May 13, 2013

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2013

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-35409

**Merrimack Pharmaceuticals, Inc.**

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**04-3210530**

(I.R.S. Employer Identification Number)

**One Kendall Square, Suite B7201**

**Cambridge, MA**

(Address of principal executive offices)

**02139**

(Zip Code)

**(617) 441-1000**

(Registrant's telephone number, including area code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller reporting company

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

As of April 30, 2013, there were 96,087,920 shares of Common Stock, \$0.01 par value per share, outstanding.

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I</b>	
<b>FINANCIAL INFORMATION</b>	
Item 1.	3
Financial Statements.	
Condensed Consolidated Balance Sheets    December 31, 2012 and March 31, 2013 (unaudited)	3
Condensed Consolidated Statements of Comprehensive Loss    Three months ended March 31, 2012 and 2013 (unaudited)	4
Condensed Consolidated Statements of Cash Flows    Three months ended March 31, 2012 and 2013 (unaudited)	5
Notes to Condensed Consolidated Financial Statements (unaudited)	6
Item 2.	19
Management's Discussion and Analysis of Financial Condition and Results of Operations.	
Item 3.	32
Quantitative and Qualitative Disclosures About Market Risk.	
Item 4.	33
Controls and Procedures.	
<b>PART II</b>	
<b>OTHER INFORMATION</b>	
Item 1.	34
Legal Proceedings.	
Item 1A.	34
Risk Factors.	
Item 2.	68
Unregistered Sales of Equity Securities and Use of Proceeds.	
Item 6.	68
Exhibits.	
Signatures	69
Exhibit Index	70

### 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, will 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;
- our collaborations with PharmaEngine, Inc. related to MM-398 and with Sanofi related to MM-121;
- 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;

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- 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 or investments that we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to the 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)	December 31, 2012	March 31, 2013
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 37,714	\$ 28,435
Available-for-sale securities	72,238	58,252
Restricted cash	100	100
Accounts receivable	9,267	9,798
Prepaid expenses and other current assets	8,982	10,167
Total current assets	128,301	106,752
Restricted cash	528	528
Property and equipment, net	6,297	7,307
Other assets	1,068	34
Intangible assets, net	2,165	2,085
In-process research and development	7,010	7,010
Goodwill	3,605	3,605
<b>Total assets</b>	<b>\$ 148,974</b>	<b>\$ 127,321</b>
<b>Liabilities, Non-Controlling Interest (Deficit) and Stockholders Deficit</b>		
Current liabilities:		
Accounts payable, accrued expenses and other	\$ 24,936	\$ 31,184
Deferred revenues	9,350	8,890
Deferred rent	1,153	1,243
Deferred tax incentives	512	512
Derivative liability	196	231
Loans payable	2,373	6,254
Total current liabilities	38,520	48,314
Deferred revenues	71,114	68,509
Deferred rent	6,323	6,735
Deferred tax incentives	755	627
Loans payable	37,482	34,076
Accrued interest	1,200	1,200
Total liabilities	155,394	159,461
Commitments and contingencies (Note 10)		
Non-controlling interest (deficit)	97	(73)
Stockholders deficit:		
Preferred stock, \$0.01 par value: 10,000 shares authorized at December 31, 2012 and March 31, 2013; no shares issued or outstanding at December 31, 2012 and March 31, 2013		

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

Common stock, \$0.01 par value: 200,000 shares authorized at December 31, 2012 and March 31, 2013; 95,825 and 95,948 shares issued and outstanding at December 31, 2012 and March 31, 2013, respectively

	958	959
Additional paid-in capital	434,679	437,263
Accumulated other comprehensive loss	(38)	(20)
Accumulated deficit	(442,116)	(470,269)
Total stockholders' deficit	(6,517)	(32,067)
<b>Total liabilities, non-controlling interest (deficit) and stockholders' deficit</b>	<b>\$ 148,974</b>	<b>\$ 127,321</b>

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



**Merrimack Pharmaceuticals, Inc.**  
**Condensed Consolidated Statements of Comprehensive Loss**

(in thousands, except per share amounts) (unaudited)	Three months ended	
	2012	March 31, 2013
Collaboration revenues	\$ 11,344	\$ 14,655
Operating expenses:		
Research and development	31,651	36,989
General and administrative	3,728	4,932
Total operating expenses	35,379	41,921
Loss from operations	(24,035)	(27,266)
Other income and expenses		
Interest income	9	52
Interest expense	(1)	(1,220)
Other, net	625	111
Net loss	(23,402)	(28,323)
Less net loss attributable to non-controlling interest	(118)	(170)
Net loss attributable to Merrimack Pharmaceuticals, Inc.	\$ (23,284)	\$ (28,153)
Other comprehensive income:		
Unrealized gain on available-for-sale securities		18
Other comprehensive income		18
Comprehensive loss	(23,284)	(28,135)
Net loss per share available to common stockholders basic and diluted	\$ (2.14)	\$ (0.29)
Weighted-average common shares used in computing net loss per share available to common stockholders basic and diluted	11,846	95,879

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

**Merrimack Pharmaceuticals, Inc.**  
**Condensed Consolidated Statements of Cash Flows**

(in thousands) (unaudited)	Three months ended March 31,	
	2012	2013
<b>Cash flows from operating activities</b>		
Net loss	\$ (23,402)	\$ (28,323)
Adjustments to reconcile net loss to net cash used in operating activities		
Non-cash interest expense		234
Remeasurement of convertible preferred stock warrants	(559)	
Depreciation and amortization	1,201	700
Stock-based compensation	1,339	2,386
Changes in operating assets and liabilities		
Purchased premiums and interest on available-for-sale securities		(291)
Accounts receivable	1,446	(531)
Accounts payable, accrued expenses and other	(2,356)	6,910
Deferred revenues	3,362	(3,065)
Other assets and liabilities, net	(434)	784
Net cash used in operating activities	(19,403)	(21,196)
<b>Cash flows from investing activities</b>		
Purchases of available-for-sale securities		(7,090)
Proceeds from maturities of available-for-sale securities		20,950
Purchases of property and equipment	(326)	(2,354)
Other investing activities, net	(100)	
Net cash (used in) provided by investing activities	(426)	11,506
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock	148	199
Proceeds from convertible notes issued by subsidiary, net of issuance costs		274
Other financing activities, net	(218)	(62)
Net cash (used in) provided by financing activities	(70)	411
Net decrease in cash and cash equivalents	(19,899)	(9,279)
Cash and cash equivalents, beginning of period	50,454	37,714
Cash and cash equivalents, end of period	30,555	28,435
<b>Non-cash investing and financing activities</b>		
Changes in deferred financing costs included in ending accounts payable, accrued expenses and other	505	
Issuance of derivative liability		35
Changes in property and equipment in accounts payable and accrued expenses		(662)
Disposal of fully depreciated assets		50
<b>Supplemental disclosure of cash flows</b>		
Cash paid for interest	\$	\$ 998

*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. 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's discovery and development effort is driven by Network Biology, which is its proprietary systems biology-based approach to biomedical research.

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 March 31, 2013, the Company had unrestricted cash and cash equivalents and available-for-sale securities of \$86.7 million. The Company expects that its existing unrestricted cash and cash equivalents and available-for-sale securities on hand as of March 31, 2013, anticipated interest income, and research and development and manufacturing funding under its license and collaboration agreement with Sanofi related to MM-121 will enable the Company to fund its operating expenses and capital expenditure requirements into 2014.

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**

**Basis of Presentation and Consolidation**

The accompanying condensed consolidated financial statements as of March 31, 2013, and for the three months ended March 31, 2012 and 2013, have been prepared in accordance with the rules and

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

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, 2012 filed with the SEC on March 20, 2013.

The information presented in the condensed consolidated financial statements and related notes as of March 31, 2013, and for the three months ended March 31, 2012 and 2013, is unaudited. The December 31, 2012 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 months ended March 31, 2013 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2013, or any future period.

These condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Merrimack Pharmaceuticals (Bermuda) Ltd. The Company also consolidates its 74% 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 74% as of December 31, 2012 and March 31, 2013. The consolidated financial statement activity related to Silver Creek was as follows:

(in thousands)	Non-Controlling Interest	
Balance at December 31, 2011	\$	574
Net loss attributable to Silver Creek		(118)
Balance at March 31, 2012	\$	456

	Non-Controlling Interest (Deficit)	
Balance at December 31, 2012	\$	97
Net loss attributable to Silver Creek		(170)
Balance at March 31, 2013	\$	(73)

### 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 significant estimates in these condensed consolidated financial statements include revenue recognition, periods of meaningful use of licensed products, useful lives with respect to long-lived assets and intangibles and the valuation of stock options, convertible preferred stock warrants, contingencies, accrued expenses, intangible assets, goodwill, in-process research and development, derivative liability and tax valuation reserves. 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 as a component of stockholders' equity 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 securities during the three months ended March 31, 2013.

Available-for-sale securities, all of which have maturities of twelve months or less, as of March 31, 2013 consisted of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
<b>March 31, 2013:</b>				
Certificate of deposit	\$ 240	\$	\$	\$ 240
Commercial paper	14,487	2	(6)	14,483
Corporate debt securities	43,545	1	(17)	43,529
Total	\$ 58,272	\$ 3	\$ (23)	\$ 58,252

The aggregate fair value of securities held by the Company in an unrealized loss position for less than 12 months as of March 31, 2013 was \$45.0 million, representing 18 securities. To determine whether an other-than-temporary impairment exists, 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 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 where 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 amount of the loss recognized in other income (expense).

Available-for-sale securities in an unrealized loss position as of March 31, 2013 consisted of the following:

	Aggregate Fair Value	Unrealized Losses
	(in thousands)	
<b>March 31, 2013:</b>		
Commercial paper	\$ 9,487	\$ (6)
Corporate debt securities	35,505	(17)
	\$ 44,992	\$ (23)

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 recovery of their amortized cost bases, which may be





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 March 31, 2013.

### **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 off-balance sheet concentrations of credit risk such as foreign currency exchange contracts, options contracts or other hedging arrangements.

### **Derivative Liability**

In December 2012, the Company's majority owned subsidiary, Silver Creek, entered into a Note Purchase Agreement pursuant to which it issued convertible notes to various lenders in aggregate principal amounts of \$1.6 million in December 2012 and \$0.3 million in February 2013. The principal and accrued interest are convertible into Silver Creek's next qualifying series of preferred stock at a discount or into Silver Creek's existing preferred stock upon maturity of the notes on December 31, 2013, whichever occurs first. Upon issuance, the Company determined that the underlying convertible notes represented share-settled debt and the potential conversion of the convertible notes into Silver Creek's next qualifying series of preferred stock at a discount met the definition of a derivative. The Company estimated the value of the derivative liability issued in connection with the convertible notes payable at \$196,000 as of December 31, 2012 and \$231,000 as of March 31, 2013. The derivatives are classified as a liability on the Company's condensed consolidated balance sheet and are remeasured at each reporting period with changes in fair value being recognized in earnings.

### **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 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 new 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, amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual method. 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. The Company also adopted guidance that permits the recognition of revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the



milestone meets certain criteria and is considered to be substantive. The Company did not enter into any significant multiple element arrangements or materially modify any of its existing multiple element arrangements during the year ended December 31, 2012 or the three months ended March 31, 2013. The Company's existing license and collaboration agreements continue to be accounted for under previously issued revenue recognition guidance for multiple element arrangements and milestone revenue recognition, as described below.

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 counter-party 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 nonemployees 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.



**Recent Accounting Pronouncements**

In February 2013, the Financial Accounting Standards Board issued amendments to the accounting guidance for presentation of comprehensive income to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments do not change the current requirements for reporting net income or other comprehensive income, but do require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where the net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under GAAP that provide additional detail about these amounts. For public companies, these amendments are effective prospectively for reporting periods beginning after December 15, 2012. There were no amounts reclassified out of accumulated other comprehensive income during the three months ended March 31, 2013.

**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. For purposes of this calculation, convertible preferred stock, 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 following table presents the computation of basic and diluted net loss per share available to common stockholders for the three months ended March 31, 2012 and 2013:

(in thousands, except per share amount)	Three months ended March 31,	
	2012	2013
<b>Net Loss Per Share:</b>		
Numerator:		
Net loss attributable to Merrimack Pharmaceuticals, Inc.	\$ (23,284)	\$ (28,153)
Plus: Unaccreted dividends on convertible preferred stock	(2,040)	
Net loss available to common stockholders basic and diluted	(25,324)	(28,153)
Denominator:		
Weighted-average common shares basic and diluted	11,846	95,879
Net loss per share available to common stockholders basic and diluted	\$ (2.14)	\$ (0.29)

The following common stock equivalents of potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as of March 31, 2012 and 2013, as the Company recorded a net loss in all periods and, therefore, they would be anti-dilutive:

(in thousands)	As of March 31,	
	2012	2013
Convertible preferred stock	66,256	
Options to purchase common stock	17,515	20,664
Convertible preferred stock warrants	302	
Common stock warrants	2,631	2,779

#### 4. License and Collaboration Agreements

##### Sanofi

On September 30, 2009, the Company entered into a license and collaboration agreement with Sanofi for the development and commercialization of a drug candidate being developed by the Company under the name MM-121. The agreement became effective on November 10, 2009 and Sanofi paid the Company a nonrefundable, noncreditable upfront license fee of \$60.0 million. During the years ended 2010 and 2011, the Company received a total of \$20.0 million in milestone payments associated with dosing the first patients in Phase 2 clinical trials in breast cancer and non-small cell lung cancer. During the first quarter of 2012, the Company received an additional milestone payment of \$5.0 million associated with dosing the first patient in a Phase 2 clinical trial in ovarian cancer. The Company is eligible to receive additional future development, regulatory and sales milestone payments as well as future royalty payments depending on the success of MM-121.

Under the agreement, Sanofi is responsible for all MM-121 development and manufacturing costs. The Company has the right, but not the obligation, to co-promote MM-121 in the United States and to participate in the development of MM-121 through Phase 2 proof of concept trials. Sanofi reimburses the Company for direct costs incurred in development and compensates the Company for its internal development efforts based on a full time equivalent ( FTE ) rate. Also as part of the agreement, the Company was required to manufacture certain quantities of MM-121 and, at Sanofi's and the Company's option, may continue to manufacture additional quantities of MM-121 in the future. Sanofi reimburses the Company for direct costs incurred in manufacturing and compensates the Company for its internal manufacturing efforts based on an FTE rate. The Company satisfied its manufacturing obligations during 2010 and has elected to continue to manufacture quantities of MM-121.

The Company applied revenue recognition guidance to determine whether the performance obligations under this collaboration, including the license, the right to future technology, back-up compounds, participation on steering committees, development services and manufacturing services, could be accounted for separately or as a single unit of accounting. The Company determined that its development services performance obligation is considered a separate unit of accounting, as it is set at the Company's option, has stand-alone value and the FTE rate is considered fair value. Therefore, the Company recognizes cost reimbursements for MM-121 development services as incurred. The Company determined that the license, the right to future technology, back-up compounds, participation on steering committees and manufacturing services performance obligations 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 is currently estimated to be 12 years from the effective date of the agreement. Under this model, when a milestone is earned or manufacturing services are rendered and product is delivered, revenue is immediately recognized on a pro-rata basis in the period the milestone was achieved or product was delivered based on the time elapsed from the effective date of the agreement. Thereafter, the remaining portion is recognized on a straight-line basis over the remaining development period.

During the three months ended March 31, 2012 and 2013, the Company recognized revenue based on the following components of the Sanofi agreement:

(in thousands)	Three months ended March 31,	
	2012	2013
Upfront payment	\$ 1,250	\$ 1,250
Milestone payments	1,412	521
Development services	8,142	11,590
Manufacturing services and other	521	741
Total	\$ 11,325	\$ 14,102

As of December 31, 2012 and March 31, 2013, the Company maintained the following assets and liabilities related to the Sanofi agreement:

(in thousands)	December 31, 2012	March 31, 2013
Accounts receivable, billed	\$ 1,577	\$ 5,217
Accounts receivable, unbilled	7,690	4,579
Deferred revenue	79,913	77,399

#### GTC Biotherapeutics, Inc.

In July 2009, the Company entered into a license agreement with GTC Biotherapeutics, Inc. ( GTC ) for the development of MM-093 by GTC. On March 19, 2013, GTC terminated the license agreement. As a result, the Company recognized the remaining \$0.6 million of deferred revenue related to this license agreement during the first quarter of 2013.

#### PharmaEngine, Inc.

On May 5, 2011, the Company entered into an assignment, sublicense and collaboration agreement with PharmaEngine, Inc. ( PharmaEngine ) under which the Company reacquired rights in Europe and certain countries in Asia to a drug being developed under the name MM-398. In exchange, the Company agreed to pay PharmaEngine a nonrefundable, noncreditable upfront payment of \$10.0 million and will be required to make up to an aggregate of \$80.0 million in development and regulatory





milestone payments and \$130.0 million in sales milestone payments upon the achievement of specified development, regulatory and annual net sales milestones. During the first quarter of 2012, the Company paid a milestone of \$5.0 million under the collaboration agreement with PharmaEngine 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. The Company is responsible for all future development costs of MM-398 except those required specifically for regulatory approval in Taiwan.

During the three months ended March 31, 2012 and 2013, the Company recognized research and development expenses of \$5.3 million and \$0.3 million, respectively, related to the agreement with PharmaEngine. These amounts included a \$5.0 million milestone payment expensed during the first quarter of 2012.

## 5. Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, available-for-sale securities, prepaid expenses, accounts receivable, accounts payable and accrued expenses and other short-term assets and liabilities approximate fair value due to the short-term nature of these instruments. The derivative liability is also carried at fair value.

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.

The following tables show assets and liabilities measured at fair value on a recurring basis as of December 31, 2012 and March 31, 2013 and the input categories associated with those assets and liabilities:

### As of December 31, 2012 (in thousands)

	Level 1	Level 2	Level 3
<b>Assets:</b>			
Cash equivalents money market funds	\$ 25,668	\$	\$
Cash equivalents certificates of deposit		480	
Cash equivalents corporate debt securities		5,017	
Investments certificates of deposit		240	
Investments commercial paper		12,465	
Investments corporate debt securities		59,533	
<b>Liabilities:</b>			
Derivative liability			196

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

As of March 31, 2013

(in thousands)	Level 1	Level 2	Level 3
<b>Assets:</b>			
Cash equivalents money market funds	\$ 13,667	\$	\$
Investments certificates of deposit		240	
Investments commercial paper		14,483	
Investments corporate debt securities		43,529	
<b>Liabilities:</b>			
Derivative liability			231

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 loss. The amortized cost of securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. The fair value of the derivative liability as of December 31, 2012 and March 31, 2013 was determined using a probability-weighted valuation model based upon the likelihood of Silver Creek achieving a qualified financing.

The following table provides quantitative information associated with the fair value measurement of the Company's Level 3 inputs:

	Fair Value as of March 31, 2013 (in thousands)	Valuation Technique	Unobservable Input	Point Estimate
Derivative Liability	\$ 231	Probability-weighted	Estimated probability of Silver Creek qualified financing(s) prior to December 31, 2013	50%

The significant unobservable input used in the fair value measurement of the Company's derivative liability is the probability of Silver Creek's successful achievement of aggregate financings of at least \$4.0 million of gross proceeds prior to December 31, 2013.

The following table provides a roll-forward of the fair value of the derivative liability categorized as Level 3 instruments, for the three months ended March 31, 2013:

(in thousands)		Derivative Liability
Balance, December 31, 2012	\$	196
Portion of convertible notes issued in February 2013 allocated to derivative		35
Balance, March 31, 2013	\$	231

## 6. Accounts Payable, Accrued Expenses and Other

Accounts payable, accrued expenses and other as of December 31, 2012 and March 31, 2013 consisted of the following:

(in thousands)	December 31, 2012		March 31, 2013	
Accounts payable	\$	283	\$	6,459
Accrued goods and services		17,615		19,335
Accrued payroll and related benefits		5,853		4,245
Accrued interest		306		390
Accrued dividends payable		28		28
Contractual liability		851		727
Total accounts payable, accrued expenses and other	\$	24,936	\$	31,184

## 7. Debt

In November 2012, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Hercules Technology Growth Capital, Inc. pursuant to which the Company received loans in the aggregate principal amount of \$40.0 million in 2012. The Company's obligations associated with the Loan Agreement are secured by 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 provides for interest-only payments for twelve months and repayment of the aggregate outstanding principal balance of the loans in monthly installments starting on December 1, 2013 and continuing through May 1, 2016. However, if the Company receives aggregate gross proceeds of at least \$75 million in one or more transactions prior to December 1, 2013, the Company may elect to extend the interest-only period by six months so that the aggregate outstanding principal balance of the loans would be repaid in monthly installments starting on June 1, 2014 and continuing through November 1, 2016. For the three months ended March 31, 2013, interest expense related to the outstanding principal balance of the loans was \$1.1 million. Upon full repayment or maturity of the loans, the Company is required to pay a fee of \$1.2 million, which is recorded as a long-term liability on the condensed consolidated balance sheets.

As of March 31, 2013, the Company had outstanding borrowings of \$38.7 million, net of debt discounts of \$1.4 million. Amortization of the debt discounts, which are recorded as interest expense, was \$0.2 million for the three months ended March 31, 2013.

*Silver Creek Convertible Notes*

In December 2012, as described in Note 2 Derivative Liability, the Company's majority owned subsidiary, Silver Creek, entered into a Note Purchase Agreement pursuant to which it issued convertible notes to various lenders in aggregate principal amounts of \$1.6 million in December 2012 and

\$0.3 million in February 2013. As of March 31, 2013, Silver Creek had outstanding borrowings of \$1.6 million, net of debt discounts of \$0.2 million. Amortization of the debt discounts, which are recorded as interest expense, was \$0.1 million for the three months ended March 31, 2013.

## 8. Common Stock

As of December 31, 2012 and March 31, 2013, the Company had 200.0 million shares of \$0.01 par value common stock authorized. There were 95,825,000 and 95,948,000 shares of common stock issued and outstanding as of December 31, 2012 and March 31, 2013, respectively. The shares reserved for future issuance as of December 31, 2012 and March 31, 2013 consisted of the following:

(in thousands)	December 31, 2012	March 31, 2013
Common stock warrants	2,842	2,779
Options to purchase common stock	18,066	20,664
	20,908	23,443

## 9. Stock-Based Compensation

As of December 31, 2012, there were 1.3 million shares of common stock available to be issued under the 2011 Stock Incentive Plan, (the 2011 Plan ). The 2011 Plan is administered by the Board of Directors of the Company 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 2013, 3.4 million shares of common stock became available for grant to employees, officers, directors and consultants under the 2011 Plan.

During the three months ended March 31, 2012 the Company did not issue options to purchase shares of common stock. During the three months ended March 31, 2013, the Company issued options to purchase 2.7 million shares of common stock. At March 31, 2013, there were 1.9 million shares remaining available for grant under the 2011 Plan.

The weighted-average assumptions used to estimate the fair value of options granted to employees at the date of grant for the three months ended 2013 were as follows:

	Three months ended March 31, 2013
Risk-free interest rate	1.1%
Expected dividend yield	0%
Expected term	5.8-5.9 years
Expected volatility	67%

These options generally vest over a three-year period for employees. The Company recognized stock-based compensation expense as follows for the three months ended March 31, 2012 and 2013:

(in thousands)	Three months ended March 31,	
	2012	2013
Employee awards:		
Research and development	\$ 909	\$ 1,284
General and administrative	430	1,090
Stock-based compensation for employee awards	1,339	2,374
Stock-based compensation for non-employee awards		12
Total stock-based compensation	\$ 1,339	\$ 2,386

The following table summarizes stock option activity during the three months ended March 31, 2013:

(in thousands, except per share amounts)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, December 31, 2012	18,066	\$ 3.50	6.54	\$ 51,486
Granted	2,719	\$ 6.35		
Exercised	(90)	\$ 2.18		
Forfeited	(31)	\$ 6.76		
Outstanding, March 31, 2013	20,664	\$ 3.87	6.71	\$ 51,276
Exercisable, March 31, 2013	14,177	\$ 2.66	5.52	\$ 49,725
Vested and expected to vest, March 31, 2013	20,154	\$ 3.80	6.64	\$ 51,249

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 as of the respective balance sheet date.

## 10. Commitments and Contingencies

### Operating leases

The Company leases its office, laboratory and manufacturing space under non-cancellable operating leases. During March 2013, the Company entered into a facility lease amendment to further expand its office, laboratory and manufacturing space. The amendment leased additional space effective March 2013 and is co-terminus with the existing lease. The aggregate additional rent due over the term of the lease amendment is approximately \$2.6 million. As part of this amendment, the landlord agreed to reimburse the Company for an additional portion of tenant improvements made to the facility, up to a total of \$0.6 million. Aggregate landlord reimbursable tenant improvements outstanding under the



existing lease and the lease amendment as of March 31, 2013 is \$6.8 million, which are recorded within other current assets on the condensed consolidated balance sheets.

## 11. Subsequent Events

In April 2013, the Company received an award of \$0.5 million of tax incentives from the Massachusetts Life Sciences Center, which allows the Company to monetize approximately \$0.4 million of state research and development tax credits. In exchange for these incentives, the Company pledged to hire an incremental 20 employees and to maintain the additional headcount through at least December 31, 2017. Failure to do so could result in the Company being required to repay some or all of these incentives. The Company has deferred and will amortize the benefit of this monetization on a straight-line basis over the five-year performance period, commencing with a cumulative catch-up when the pledge is achieved.

## 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, 2012 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. 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 conducting a Phase 3 clinical trial.

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, an initial public offering and a secured debt financing. Through March 31, 2013, we have received \$268.2 million from the sale of convertible preferred stock and warrants, \$98.1 million of net proceeds from the sale of common stock during our initial public offering, \$39.6 million of net proceeds from a secured debt financing and \$187.0 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaborations. As of March 31, 2013, we had unrestricted cash and cash equivalents and available-for-sale securities of \$86.7 million, which, together with anticipated interest income and research and development and manufacturing funding under our license and collaboration agreement with Sanofi related to MM-121, we expect will enable us to fund our operating expenses and capital expenditure requirements into 2014.



We have never been profitable and, as of March 31, 2013, we had an accumulated deficit of \$470.3 million. Our net loss was \$23.4 million and \$28.3 million for the three months ended March 31, 2012 and 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, 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.

We are also considering arrangements to use our manufacturing capabilities to manufacture drug product on behalf of third party pharmaceutical companies. We have no current agreements or commitments for any such arrangements.

### **Strategic Partnerships, Licenses and Collaborations**

#### ***Sanofi***

In September 2009, we entered into a license and collaboration agreement with Sanofi for the development and commercialization of MM-121. Under this agreement, we granted Sanofi an exclusive, royalty-bearing, worldwide right and license to develop and commercialize MM-121 in exchange for payment by Sanofi of an upfront license fee of \$60.0 million, up to \$410.0 million in potential development and regulatory milestone payments, of which we have already received \$25.0 million, up to \$60.0 million in potential sales milestone payments and tiered, escalating royalties beginning in the sub-teen double digits based on net sales of MM-121 in the United States and beginning in the high single digits based on net sales of MM-121 outside the United States. We have the right, but not the obligation, to co-promote and commercialize MM-121 in the United States and to participate in the development of MM-121 through Phase 2 proof of concept trials, which we are currently conducting. If we co-promote MM-121 in the United States, we will be responsible for paying our sales force costs and a specified percentage of direct medical affairs, marketing and promotion costs for MM-121 in the United States and will be eligible to receive tiered, escalating royalties beginning in the high teens based on net sales of MM-121 in the United States. We are also entitled to an increase in the royalty rate if a diagnostic product is actually used with MM-121 in the treatment of solid tumor indications. Sanofi is responsible for all development and manufacturing costs for MM-121. Although Sanofi will ultimately be responsible for manufacturing MM-121 under the agreement, we are currently manufacturing MM-121 for use in ongoing clinical trials. Sanofi has assumed responsibility for all manufacturing of MM-121 for Phase 3 clinical trials. 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.

The timing of cash received from Sanofi differs from revenue recognized for financial statement purposes. We recognize revenue for development services as incurred and recognize revenue for the upfront payment, milestone payments and manufacturing services using the contingency-adjusted performance model over the expected development period, which is currently estimated to be 12 years from the effective date of our agreement with Sanofi. During the three months ended March 31, 2012 and 2013, we recognized revenue based on the following components of the Sanofi agreement:

(in thousands)	Three months ended March 31,	
	2012	2013
Upfront payment	\$ 1,250	\$ 1,250
Milestone payments	1,412	521
Development services	8,142	11,590
Manufacturing services and other	521	741
Total	\$ 11,325	\$ 14,102

***GTC Biotherapeutics, Inc.***

In July 2009, we entered into a license agreement with GTC Biotherapeutics, Inc., or GTC, for the development of MM-093 by GTC. On March 19, 2013, GTC terminated the license agreement. As a result, we recognized the remaining \$0.6 million of deferred revenue related to this license agreement during the first quarter of 2013.

**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 under which we reacquired all previously licensed rights for MM-398, other than rights to commercialize MM-398 in Taiwan. As a result, we now have the exclusive right to commercialize MM-398 in all territories in the world, except for Taiwan, where PharmaEngine has an exclusive commercialization right. Upon entering into the May 2011 agreement with PharmaEngine, we paid PharmaEngine a \$10.0 million upfront license fee. In addition, we made a milestone payment of \$5.0 million to PharmaEngine in connection with dosing the first patient in our Phase 3 clinical trial of MM-398, which occurred and was paid in the first quarter of 2012. We may be required to make up to an aggregate of \$75.0 million in additional development and regulatory milestone payments and \$130.0 million in additional sales milestone payments to PharmaEngine upon the achievement of specified development, regulatory and annual net sales milestones. 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 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 May 2011 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 March 31, 2012 and 2013, we recognized research and development expense of \$5.3 million and \$0.3 million, respectively, under the May 2011 agreement with PharmaEngine.

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, primarily with Sanofi, 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 will fluctuate from 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, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales until 2014 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.

### 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.

(in thousands)	Indication	Current stage of development	Three months ended March 31,		
			2012		2013
MM-398	Cancer	Phase 3	\$ 7,794	\$	7,270
MM-121	Cancer	Phase 2	8,193		12,062
MM-111	Cancer	Phase 1/Phase 2 planned	1,903		4,267
MM-302	Cancer	Phase 1	1,529		1,469
MM-151	Cancer	Phase 1	2,816		1,740
MM-141	Cancer	Phase 1	2,782		1,386
Preclinical, general research and discovery			5,725		7,511
Stock compensation			909		1,284
Total research and development expense			\$ 31,651	\$	36,989

### MM-398

MM-398 is currently being evaluated in a Phase 3 clinical trial in patients with metastatic pancreatic cancer whose cancer has progressed on treatment with gemcitabine. Our current estimate of the



remaining external costs associated with completing the Phase 3 clinical trial is between \$12.0 million and \$17.0 million. We are 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 investigator sponsored trials are ongoing in which the majority of the total clinical trial costs are paid for by the investigators. Investigator sponsored trials include a Phase 2 clinical trial in colorectal cancer and a Phase 1 clinical trial in glioma.

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 trial. We may be required to make up to an aggregate of \$75.0 million in additional development and regulatory milestone payments and \$130.0 million in additional sales milestone payments to PharmaEngine upon the achievement of specified development, regulatory and annual net sales milestones. 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 our net sales of MM-398 in these territories.

#### *MM-121*

We have entered into a license and collaboration agreement with Sanofi related to MM-121. Under the terms of the agreement, we are currently responsible for executing clinical trials through Phase 2 proof of concept trials for each indication. Although Sanofi will ultimately be responsible for manufacturing MM-121 under the license and collaboration agreement, we are currently manufacturing MM-121 for use in ongoing clinical trials. Sanofi has assumed responsibility for all manufacturing of MM-121 for Phase 3 clinical trials. All expenses related to manufacturing are required to be reimbursed by Sanofi. Sanofi pays a portion of the estimated manufacturing campaign costs upfront and the remainder during and upon completion of the manufacturing campaign in accordance with an agreed upon budget. We separately record revenue and expenses on a gross basis under this arrangement. Sanofi is responsible for all development and manufacturing costs of MM-121. We are currently conducting four Phase 2 clinical trials and three Phase 1 clinical trials of MM-121 in multiple cancer types.

#### *MM-111*

We are currently preparing to initiate a Phase 2 clinical trial of MM-111 in gastric cancer and are conducting two Phase 1 clinical trials of MM-111 in multiple cancer types.

#### *MM-302*

We are currently conducting one Phase 1 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. During the first quarter of 2012, we made a \$1.5 million payment under our collaboration agreement with Adimab LLC.

*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 executive, 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.

***Interest expense***

Interest expense primarily consists of interest recorded on our loans payable.

***Other income (expense)***

Other income (expense) primarily consists of gains and losses on the change in value and time to expiration of convertible preferred stock warrants, 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 derivative liabilities, useful lives with respect to long-lived assets and intangibles, valuation of stock options, convertible preferred stock warrants, 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.

While our significant accounting policies are more fully described in Note 2 to the consolidated financial statements appearing in our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 20, 2013, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

*Revenue recognition*

We enter into biopharmaceutical product development agreements with collaborators for the research and development of therapeutic and diagnostic products. The terms of these agreements may include nonrefundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. We assess these

multiple elements in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification 605, *Revenue Recognition*, in order to determine whether particular components of the arrangement represent separate units of accounting.

In January 2011, we adopted new 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, amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual method. 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. We also adopted guidance that permits the recognition of revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets certain criteria and is considered to be substantive. We did not enter into any significant multiple element arrangements or materially modify any of our existing multiple element arrangements during the three months ended March 31, 2012 and 2013. Our existing collaboration agreements continue to be accounted for under previously issued revenue recognition guidance for multiple element arrangements and milestone revenue recognition, as described below.

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

Our 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 we have performed the performance obligations to date over the total estimated time to complete the performance obligations, multiplied by the amount of the milestone payment, is 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 approval are not considered probable of being achieved until such approval is received. Milestones tied to counterparty performance are not included in our revenue model until the performance conditions are met.

We will recognize royalty revenue upon the sale of the related products, provided we have no remaining performance obligations under the arrangement. To date, we have not received any royalty payments or recognized any royalty revenue.

We record deferred revenue when payments are received in advance of the culmination of the earnings process. This revenue is recognized in future periods when the applicable revenue recognition criteria have been met.

### *Accrued expenses*

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves identifying services that have been performed on our behalf and estimating the level of services performed and the associated costs incurred for such services where we have not yet been invoiced or otherwise notified of actual cost. We record these estimates in our condensed consolidated financial statements as of each balance sheet date. Examples of estimated accrued expenses include:

- fees due to contract research organizations in connection with preclinical and toxicology studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials; and
- professional service fees.

In accruing service fees, we estimate the time period over which services will be provided and the level of effort in each period. If the actual timing of the provision of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. In the event that we do not identify costs that have been incurred or we under or overestimate the level of services performed or the costs of such services, our actual expenses could differ from such estimates. The date on which some services commence, the level of services performed on or before a given date and the cost of such services are often subjective determinations. We make estimates based upon the facts and circumstances known to us at the time and in accordance with GAAP. There have been no material changes in estimates for the periods presented.

### *Stock-based compensation*

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based awards made to employees, including stock options, based on the estimated grant date fair values. For employees, we use the straight-line method to allocate compensation expense to reporting periods over each optionee's requisite service period, which is generally the vesting period. For non-employees, we record awards at fair value, periodically remeasure awards to reflect the current fair value at each reporting period and recognize expense over the related service period. When applicable, we account for these equity instruments based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

We estimate the fair value of stock-based awards to employees and non-employees using the Black-Scholes option valuation model. Determining the fair value of stock-based awards requires the use of highly subjective assumptions, including volatility, the calculation of expected term, risk free interest rate and the fair value of the underlying common stock on the date of grant, among other inputs. The assumptions used in determining the fair value of stock-based awards represent our best estimates, which involve inherent uncertainties and the application of judgment. As a result, if factors change, and different assumptions are used, our level of stock-based compensation could be materially different in the future.

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

There were no options granted during the three month period ended March 31, 2012. There were 2.7 million options granted during the three month period ended March 31, 2013. The weighted-average assumptions used to estimate the fair value of options granted to employees during the three months ended March 31, 2013 were as follows:

	Three months ended March 31, 2013
Risk-free interest rate	1.1%
Expected dividend yield	0%
Expected term	5.8-5.9 years
Expected volatility	67%

The expected volatility rate that we use to value stock option grants is based on historical volatilities of a peer group of similar companies whose share prices are publicly available. The peer group includes companies in the pharmaceutical and biotechnology industries in a similar stage of development with a comparable market capitalization or a similar clinical focus. Because we do not have a sufficient history to estimate the expected term, we use the simplified method for estimating the expected term. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option for each tranche. The risk-free interest rate assumption was based on zero coupon U.S. treasury instruments that had terms consistent with the expected term of the stock option grants.

We recognize compensation expense for only the portion of options that are expected to vest. Accordingly, expected future forfeiture rates of stock options have been estimated based on our historical forfeiture rate, as adjusted for known trends. Forfeitures are estimated at the time of grant. If actual forfeiture rates vary from historical rates and estimates, additional adjustments to compensation expense may be required in future periods.

### ***JOBS Act***

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. 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, or the Securities Act, 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. Additionally, we are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act.

Subject to certain conditions set forth in the JOBS Act, as an emerging growth company, we intend to rely on certain of these exemptions, including not being required to provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and 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. We may remain an emerging growth company for up to five years, until December 31, 2017, although if the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have annual gross revenues of \$1.0 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year.



**Results of Operations***Comparison of the three months ended March 31, 2012 and 2013*

(in thousands)	Three months ended March 31,	
	2012	2013
Collaboration revenues	\$ 11,344	\$ 14,655
Research and development expenses	31,651	36,989
General and administrative expenses	3,728	4,932
Loss from operations	(24,035)	(27,266)
Interest income	9	52
Interest expense	(1)	(1,220)
Other income	625	111
Net loss	\$ (23,402)	\$ (28,323)

*Collaboration revenues*

Collaboration revenues for the three months ended March 31, 2013 were \$14.7 million, compared to \$11.3 million for the three months ended March 31, 2012, an increase of \$3.4 million, or 30%. This increase resulted from increases in development services and manufacturing revenues recognized under the license and collaboration agreement with Sanofi and the recognition of deferred revenue under our license agreement with GTC.

*Research and development expenses*

Research and development expenses for the three months ended March 31, 2013 were \$37.0 million, compared to \$31.7 million for the three months ended March 31, 2012, an increase of \$5.3 million, or 17%. This increase was primarily attributable to:

- \$3.9 million of increased MM-121 spending primarily due to increased enrollment of ongoing clinical trials;
- \$2.4 million of increased MM-111 spending primarily due to the preparation to initiate a Phase 2 clinical trial; and
- \$1.8 million of increased spending 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.

These increases were partially offset by the following decreases:





- \$1.4 million of decreased MM-141 spending primarily due to the absence in 2013 of IND-enabling activities that occurred in the first quarter of 2012;
- \$1.1 million of decreased MM-151 spending primarily due to the absence in 2013 of a \$1.5 million licensing payment that occurred in the first quarter of 2012, partially offset by increased clinical trial costs; and
- \$0.5 million of decreased MM-398 spending primarily due the absence in 2013 of a \$5.0 million milestone payment that occurred in the first quarter of 2012, significantly offset by increased costs related to our ongoing Phase 3 clinical trial.

*General and administrative expenses*

General and administrative expenses for the three months ended March 31, 2013 were \$4.9 million, compared to \$3.7 million for the three months ended March 31, 2012, an increase of \$1.2 million, or 32%. This increase was primarily attributable to increases in labor and labor-related costs, including stock compensation expense.

*Interest expense*

Interest expense for the three months ended March 31, 2013 was \$1.2 million, compared to an immaterial amount for the three months ended March 31, 2012. This increase was primarily attributable to the interest recorded on the loans payable from Hercules Technology Growth Capital, Inc.

*Other income*

Other income for the three months ended March 31, 2013 was \$0.1 million, compared to \$0.6 million for the three months ended March 31, 2012, a decrease of \$0.5 million. This decrease was primarily attributable to \$0.6 million associated with the March 31, 2012 remeasurement of preferred stock warrants, which were subsequently reclassified to common stock warrants upon the closing of our initial public offering in April 2012.

**Liquidity and Capital Resources**

*Sources of liquidity*

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

We have financed our operations to date primarily through private placements of our convertible preferred stock, collaborations, an initial public offering and a secured debt financing. Through March 31, 2013, we have received \$268.2 million from the sale of convertible preferred stock and warrants, \$98.1 million of net proceeds from the sale of common stock during our initial public offering, \$39.6 million of net proceeds from a secured debt financing and \$187.0 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaborations. As of March 31, 2013, we had unrestricted cash and cash equivalents and available-for-sale securities of \$86.7 million.

As of March 31, 2013, within our unrestricted cash and cash equivalents, \$1.8 million was cash and cash equivalents held by Silver Creek Pharmaceuticals, Inc., or Silver Creek, which is consolidated for financial reporting purposes. This \$1.8 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 three months ended March 31, 2012 and 2013.

(in thousands)	Three months ended March 31,	
	2012	2013
Cash used in operating activities	\$ (19,403)	\$ (21,196)
Cash used in investing activities	(426)	11,506
Cash provided by financing activities	(70)	411
Net increase (decrease) in cash and cash equivalents	\$ (19,899)	\$ (9,279)

*Operating activities*

Cash used in operating activities of \$19.4 million during the three months ended March 31, 2012 was primarily a result of our net loss of \$23.4 million, partially offset by non-cash items of \$2.0 million and changes in operating assets and liabilities of \$2.0 million, which includes receipt of a \$5.0 million milestone payment under our license and collaboration agreement with Sanofi. Cash used in operating activities of \$21.2 million during the three months ended March 31, 2013 was primarily a result of our net loss of \$28.3 million, partially offset by non-cash items of \$3.3 million and changes in operating assets and liabilities of \$3.8 million.

*Investing activities*

Cash used in investing activities during the three months ended March 31, 2012 was primarily due to the purchase of property and equipment. Cash provided by investing activities during the three months ended March 31, 2013 was primarily due to proceeds from maturities and sales of available-for-sale securities net of purchases of \$13.9 million, partially offset by \$2.4 million of property and equipment purchases.

*Financing activities*

Cash used in financing activities during the three months ended March 31, 2012 was primarily a result of the payment of deferred financing costs related to our initial public offering that closed in April 2012, partially offset by proceeds from the issuance of common stock. Cash provided by financing activities for the three months ended March 31, 2013 was primarily due to \$0.2 million of proceeds from the exercise of common stock options and \$0.3 million of proceeds from the sale and issuance of convertible notes by Silver Creek.

*Funding requirements*

As of March 31, 2013, we had unrestricted cash and cash equivalents and available-for-sale securities of \$86.7 million.

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;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize products for which we may obtain regulatory approval; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

We expect that our existing unrestricted cash and cash equivalents and available-for-sale securities on hand as of March 31, 2013, anticipated interest income, and research and development and manufacturing funding under our license and collaboration agreement with Sanofi related to MM-121 will enable us to fund our operating expenses and capital expenditure requirements into 2014. 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 Sanofi related to MM-121 and with PharmaEngine related to MM-398;
- 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; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates outside the United States and Europe.

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 Sanofi for the development and commercialization of MM-121, which is terminable by Sanofi for convenience upon 180 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***

During the first quarter of 2013, we entered into a facility lease amendment, which further expanded our office, laboratory and manufacturing space. The aggregate incremental rent due over the seven-year term of the facility lease amendment is approximately \$2.6 million.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations - Contractual obligations and commitments" in our Annual Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 20, 2013.

#### **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 February 2013, the FASB issued amendments to the accounting guidance for presentation of comprehensive income to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments do not change the current requirements for reporting net income or other comprehensive income, but do require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where the net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under GAAP that provide additional detail about these amounts. For public companies, these amendments are effective prospectively for reporting periods beginning after December 15, 2012. Other than a change in presentation, we do not believe the adoption of this guidance will have a material impact on our consolidated financial statements.

#### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**



## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

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.

On November 8, 2012, we entered into a long-term debt agreement for term loans that bears 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.

#### **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, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2013. 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 March 31, 2013, 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**

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

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 March 31, 2013 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 two ongoing opposition proceedings to European patents in the European Patent Office to narrow or invalidate the claims of patents owned by third parties. We have obtained favorable interim decisions in both oppositions, although both decisions are now under appeal. The ultimate outcome of these oppositions remains uncertain.

We filed our notice of opposition in the first proceeding, opposing a patent (EP 0896586) held by Genentech, Inc., or Genentech, in July 2007 on the grounds of added matter, insufficient disclosure, lack of novelty and lack of inventive step. Amgen Inc. and U3 Pharma GmbH also opposed the Genentech patent. If the issued claims of the Genentech patent were determined to be valid and construed to cover MM-121 or MM-111, our development and commercialization of these product candidates in Europe could be delayed or prevented. In August 2009, the European Patent Office issued a written decision rejecting several sets of Genentech's claims and upholding the patent solely on the basis of a further set of claims that we believe will not restrict the development or commercialization of MM-121 or MM-111. All parties have appealed this decision. Pending the outcome of the appeal proceedings, the original issued claims of the Genentech patent remain in effect. Each party has submitted written statements regarding the appeal to the European Patent Office. No date has been set for a hearing for the appeal.

We filed our notice of opposition in the second proceeding, opposing a patent (EP 1187634) held by Zensun (Shanghai) Science and Technology Ltd., or Zensun, in September 2008 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. No date has been set for a hearing for the appeal.

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.*

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

Since inception, we have incurred significant operating losses. Our net loss was \$28.3 million for the three months ended March 31, 2013, \$91.8 million for the year ended December 31, 2012 and \$79.7 million for the year ended December 31, 2011. As of March 31, 2013, we had an accumulated deficit of \$470.3 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, collaborations, an initial public offering 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;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize products for which we may obtain regulatory approval; 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 you to lose all or part of your investment.

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

On November 8, 2012, we entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc. The Loan and Security Agreement provided for an initial term loan advance of \$25.0 million, which closed on November 8, 2012, and an additional term loan advance of \$15.0 million, which closed on December 14, 2012. We could in the future incur additional indebtedness beyond such amount.

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;

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- 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 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.

***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 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 on hand as of March 31, 2013, anticipated interest income, and research and development and manufacturing funding under our license and collaboration agreement with Sanofi related to MM-121 will enable us to fund our operating expenses and capital expenditure requirements into 2014. 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 Sanofi related to MM-121 and PharmaEngine related to MM-398;
- 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; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates outside the United States and Europe.

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 for several years, 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 our collaboration with Sanofi for the development and commercialization of MM-121, which is terminable by Sanofi for convenience upon 180 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 February 1, 2013, we filed a registration statement on Form S-3 with the SEC to allow the issuance of our securities from time to time in one or more offerings of up to \$200,000,000 in aggregate dollar amount. This registration statement was declared effective by the SEC on February 8, 2013. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. 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 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 for at least the next several years, 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 the product, whether alone or in collaboration with others;
- acceptance of the product by patients, the medical community and third party payors;
- effectively competing with other therapies;

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- a continued acceptable safety profile of the product 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 interim results of a clinical trial do not necessarily predict final results.

For example, MM-121 did not meet its primary endpoint in one cohort of a Phase 2 clinical trial in patients with non-small cell lung cancer. MM-121 is still being evaluated in two additional non-small cell lung cancer cohorts as well as Phase 2 clinical trials for the treatment of advanced ovarian cancer, hormone-receptor positive breast cancer and HER2 negative breast cancer.

In addition, the favorable results from a Phase 2 clinical trial of MM-398 in patients with metastatic pancreatic cancer may not be predictive of success in our Phase 3 clinical trial of MM-398 for the same indication, in particular because the trials have different efficacy endpoints and the Phase 2 trial was a single arm study that did not compare MM-398 to other therapies. Our Phase 3 trial, as amended, is designed to compare the efficacy of each of MM-398 as a monotherapy and MM-398 in combination with 5-FU and leucovorin against a common control of the combination of 5-FU and leucovorin. This Phase 3 trial is based on an expected efficacy endpoint of statistically significant difference in overall survival. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and 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.

We may experience numerous unforeseen 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 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, due to a lack of efficacy in clinical trials, we suspended internal development of our product candidate MM-093, a potential therapeutic for autoimmune diseases. We subsequently terminated our development program for this product candidate and licensed it to third parties.

In addition, MM-398 is currently being evaluated in a Phase 2 clinical trial in second-line metastatic colorectal cancer, which is being conducted by GERCOR, a cooperative research group of physicians based in France. This trial was initially designed as a randomized, non-comparative trial evaluating a regimen of 5-FU, leucovorin and MM-398 and FOLFIRI, which is a regimen of 5-FU, leucovorin and irinotecan. Roche recently announced results from a Phase 3 clinical trial in second-line metastatic colorectal cancer being conducted in Europe comparing chemotherapy to chemotherapy plus bevacizumab. The results of this trial by Roche have caused some medical institutions and physicians in France to modify their clinical practice. As a result, GERCOR amended the Phase 2 clinical trial of MM-398 to include bevacizumab in both arms. The amended trial resumed accrual of patients in July 2012 and is currently ongoing.

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;



## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- 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, once completed, 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 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 a new drug application, or NDA, submission. Even if we achieve favorable results in our Phase 3 clinical trial, the FDA may nonetheless require that we conduct additional clinical trials, possibly using a different design.

Our product development costs will also increase if we experience delays in testing or approvals. 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 inappropriate 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 *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 compared to alternative treatments;
- the price we charge for our product candidates;
- convenience and ease of administration compared to alternative treatments;

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- 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. Our current plan for our oncology products, other than MM-121, for which we receive marketing approval is to market and sell these products ourselves in the United States and Europe and to establish distribution or other marketing arrangements with third parties for these products in the rest of the world. We have an option to co-promote MM-121 in the United States with Sanofi, which otherwise holds worldwide commercialization rights to this product candidate.

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.

Establishing effective sales, marketing and distribution capabilities and infrastructure in Europe may be particularly difficult for us. We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply. Many U.S.-based biopharmaceutical companies have found the process of marketing their own products in Europe to be very challenging.

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, thereby harming 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 relaxation 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.*

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

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 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 be expected to 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-121 depends substantially on our collaboration with Sanofi. If Sanofi is unable or unwilling to further develop or commercialize MM-121, or experiences significant delays in doing so, our business will be materially harmed.***

MM-121 is one of our most clinically advanced product candidates. In 2009, we entered into a license and collaboration agreement with Sanofi for the development and commercialization of MM-121. Prior to this collaboration, we did not have a history of working together with Sanofi. 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-121 is successfully commercialized. We cannot predict the success of the collaboration.

Under our license and collaboration agreement, Sanofi has significant control over the conduct and timing of development and commercialization efforts with respect to MM-121. Although we and Sanofi have approved a global development plan, Sanofi may change its development plans for MM-121 at any time. We have little control over the amount, timing and quality of resources that Sanofi devotes to the development or commercialization of MM-121. If Sanofi fails to devote sufficient financial and other resources to the development or commercialization of MM-121, the development and commercialization of MM-121 would be delayed or could fail. This would result in a delay in our receiving milestone payments or royalties with respect to MM-121 or in our not receiving such milestone payments or royalties at all.



*If we lose Sanofi as a collaborator in the development or commercialization of MM-121, it would materially harm our business.*

Sanofi has the right to terminate our agreement for the development and commercialization of MM-121, in whole or with respect to specified territories, at any time and for any reason, upon 180 days prior written notice. Sanofi 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 Sanofi 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 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, seek another collaborator or licensee for such clinical development and commercialization, or abandon the development and commercialization of MM-121.

*The successful development and commercialization of MM-398 currently depend on our collaboration with PharmaEngine. If PharmaEngine does not provide clinical trial data to us, our business may be materially harmed.*

We have a collaboration with PharmaEngine for the development of MM-398. Under this collaboration, PharmaEngine has rights to commercialize MM-398 in Taiwan, while we hold commercialization rights in all other countries, including the United States. PharmaEngine also has the opportunity to participate in the development of MM-398, for which we are reimbursing their costs. We cannot predict the success of the collaboration. The collaboration involves an allocation of rights, provides for milestone payments by us to PharmaEngine based on the achievement of specified milestones and provides for us to pay PharmaEngine royalties on sales of MM-398 in Europe and specified Asian countries if MM-398 is successfully commercialized in Europe and such specified Asian countries.

We rely on PharmaEngine to provide data and information to us from trials they have conducted and are currently conducting. This information is necessary for our development of MM-398 in the United States. If PharmaEngine does not provide this information to us, our development of MM-398 could be significantly delayed and our costs could increase significantly.

*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.*

Our business plan is to enter into distribution and other marketing arrangements for our oncology products in areas of the world outside of the United States and Europe. In addition, 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 broader development and commercialization arrangements with respect to either oncology product candidates in addition to MM-121 or product candidates in other therapeutic areas in the United States or Europe or other territories. In particular, while we expect to apply our Network Biology approach to some 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. We are also a party to a right of

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

review agreement with Sanofi pursuant to which, if we determine to enter into negotiations with a third party regarding any license, option, collaboration, joint venture or similar transaction involving any therapeutic or companion diagnostic product candidate in our pipeline, we will notify Sanofi of such opportunity. Following such



notice, Sanofi will have a specified period of time to review the opportunity and determine whether to exercise an additional right to exclusively negotiate an agreement with us with respect to such opportunity for a specified period of time. In addition, in specified circumstances, if we subsequently propose to enter into any third party agreement, we must first offer the same terms and conditions to Sanofi. Our right of review agreement with Sanofi could discourage other companies from engaging with us in discussions or negotiations regarding collaboration 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 collaboration with Sanofi, 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

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- 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 requires 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 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.

### **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 manufacturing 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, or IND, 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 fill-finish and labeling activities. 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.

We do not have any 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.

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

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-302, MM-141, MM-121 and MM-111, 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,



## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

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. Under our license and collaboration agreement with Sanofi, we are obligated, at our expense, to use commercially reasonable efforts to file and prosecute patent applications, and maintain patents, covering MM-121 in specified jurisdictions, and these patent rights are licensed to Sanofi.

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 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 determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

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.

For example, we are aware of issued U.S. patents held by Genentech broadly covering methods of producing certain types of recombinant antibodies and related compositions for antibody production that may be relevant to our development and commercialization of MM-121, MM-151 and MM-141. These patents expire in 2018. Genentech has asserted infringement claims against several pharmaceutical and biotechnology companies based on these patents. If these patents were determined to be valid and cover our product candidates, we would need to obtain a license to the patented technology, which may cause us to incur licensing related costs. However, a license to these patents may not be available on commercially reasonable terms, or at all. Our failure to obtain a license to these patents could delay or prevent our development and commercialization of our product candidates in the United States.

***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 two ongoing opposition proceedings to European patents in the European Patent Office. If we are not successful in these proceedings, we may not be able to commercialize some of our product candidates without infringing patents held by third parties.***

We are currently engaged in two ongoing opposition proceedings to European patents in the European Patent Office to narrow or invalidate the claims of patents owned by third parties. For more information, see Part II, Item 1. Legal Proceedings in this Quarterly Report on Form 10-Q. We have obtained favorable interim decisions in both oppositions, although both decisions are now under appeal. The ultimate outcome of these oppositions remains uncertain. If we are not ultimately successful in these proceedings, and the issued claims of the patents we are opposing were determined to be valid and construed to cover MM-121, MM-111 or MM-141, we may not be able to commercialize MM-121, MM-111 or MM-141 in some or all European countries without infringing such patents. If we infringe a valid claim of these patents, we would need to obtain a license to the patented technology, which may cause us to incur licensing-related costs. For example, under our license and collaboration agreement with Sanofi, we are obligated to pay all licensing costs for specified third party patent rights that we or Sanofi may in the future license for the development and commercialization of MM-121, including the patent rights that are the subject of one of these opposition proceedings. However, a license to the patents that are the subject of these opposition proceedings 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 these product candidates in some or all countries in Europe if we were found to infringe a valid claim of these patents. In addition, even if we are ultimately successful in these European opposition proceedings, such results 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 upon 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. 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, or when it will do so. 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.

***If we fail to maintain orphan drug exclusivity for MM-398, we will have to rely on other rights and protections for this product candidate.***

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. 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;
- 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; and

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- there have been proposals to decrease the reference product exclusivity from 12 years to seven years. Congress has not yet enacted any such decrease, however.

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 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 both within and outside the United States. In particular, we plan to market and sell ourselves any products for which we receive marketing approval in the European Union, rather than relying on third parties for these capabilities. 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 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 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 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

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

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 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. The company has an opportunity to respond, and the non-compliance letter and company response will 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 applicable federal and state agencies issue 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 or finalize the existing 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;

Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- 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 control or 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 control or 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 control or 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 you might otherwise receive a premium for your 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;

## Edgar Filing: MERRIMACK PHARMACEUTICALS INC - Form 10-Q

- 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.

*Our stock price has been and may in the future be volatile, which could cause purchasers 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 your sole source of gain.*

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 your sole source of gain for the foreseeable future.



*Future sales of shares of our common stock, including shares issued upon the exercise of currently outstanding options and warrants, could negatively affect our stock price.*

A substantial portion of our outstanding common stock can be traded without restriction at any time. Some of these shares are currently restricted as a result of securities laws, but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future. 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 such shares, 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. The exercise of these options and warrants 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.

Furthermore, on February 1, 2013, we filed a registration statement on Form S-3 with the SEC to allow the issuance of our securities from time to time in one or more offerings of up to \$200,000,000 in aggregate dollar amount. This registration statement was declared effective by the SEC on February 8, 2013. Any sale of additional shares of our common stock or other securities could reduce the market price of our common stock.

*We are 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 an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company for up to five years, until December 31, 2017, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have annual gross revenues of \$1 billion or more in any fiscal year, we would cease to be an emerging growth company as of December 31 of the applicable year. For so long as we remain an emerging growth company, 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 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.

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

**Use of Proceeds from Registered Securities**

Our initial public offering of common stock was effected through a registration statement on Form S-1 (File No. 333-175427), which was declared effective by the SEC on March 27, 2012. We received net proceeds from the offering of approximately \$98.1 million, after deducting underwriting discounts and commissions and other offering expenses but prior to the payment of accrued dividends on our Series B convertible preferred stock.

As of March 31, 2013, we have used approximately \$4.2 million of the proceeds from the offering to pay dividends on our Series B convertible preferred stock and estimate that we have used additional proceeds as follows:

- approximately \$21.1 million to fund our ongoing clinical program for MM-398;
- approximately \$15.9 million to fund our ongoing clinical program for MM-111;
- approximately \$6.7 million to fund our ongoing clinical program for MM-302;
- approximately \$5.8 million to fund our ongoing clinical program for MM-151;
- approximately \$7.1 million to fund our ongoing clinical program for MM-141;
- approximately \$28.1 million to fund other research and development efforts; and
- approximately \$3.2 million to fund working capital, capital expenditures and other general corporate purposes.

The above estimates of proceeds used do not allocate working capital impacts resulting from the timing of payments for corporate purposes to our clinical programs or our other research and development efforts.

We have invested the unused proceeds from the offering in a variety of capital preservation investments, including money market funds and short-term, investment grade, interest-bearing corporate debt and U.S. government and U.S. government agencies securities. There has been no material change in our planned use of proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act.

**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: May 13, 2013

By:

*/s/ William A. Sullivan*  
William A. Sullivan  
Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
10.1	Fifth Amended and Restated Investor Rights Agreement, dated April 6, 2011, by and among the Registrant and the other parties thereto, as amended on March 19, 2013 (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K filed on March 20, 2013)
31.1*	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
31.2*	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
32.1*	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
32.2*	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
101.INS+	XBRL Instance Document
101.SCH+	XBRL Taxonomy Extension Schema Document
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+	XBRL Taxonomy Extension Label Linkbase Database
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document

---

\* Filed herewith.

+ Furnished herewith.