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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

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.
(Exact name of registrant as specified in its charter)

Delaware	**04-3210530**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
One Kendall Square, Suite B7201 Cambridge, MA	**02139**
(Address of principal executive offices)	**(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 July 31, 2015, there were 111,419,126 shares of Common Stock, $0.01 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

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

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

- our plans to develop and commercialize our clinical stage product candidates and companion diagnostics;
- our ongoing and planned discovery programs, preclinical studies and clinical trials;
- the timing of the completion of our clinical trials and the availability of results from such trials;
- our collaborations with Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH, which we collectively refer to as Baxalta, and PharmaEngine, Inc., or PharmaEngine, related to MM-398;
- 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 systems biology approach to drug research and development;
- the potential use of our systems biology approach in fields other than oncology; and
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing.

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

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual

future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

FINANCIAL INFORMATION

Item 1. Financial Statements.

Merrimack Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets

(in thousands, except par value) (unaudited)	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 33,664	$ 35,688
Available-for-sale securities	33,991	88,340
Restricted cash	101	101
Accounts receivable	1,762	3,313
Prepaid expenses and other current assets	5,366	4,654
Total current assets	74,884	132,096
Restricted cash	584	584
Property and equipment, net	18,273	14,502
Other assets	132	144
Intangible assets, net	1,365	1,525
In-process research and development	6,200	6,200
Goodwill	3,605	3,605
Total assets	**$ 105,043**	**$ 158,656**
Liabilities, Non-Controlling Interest and Stockholders' Deficit		
Current liabilities:		
Accounts payable, accrued expenses and other	$ 46,626	$ 37,236
Deferred revenues	59,346	59,275
Deferred rent	1,582	1,285
Long-term debt, current portion	1,058	13,346
Total current liabilities	108,612	111,142
Deferred revenues, net of current portion	9,109	35,682
Deferred rent, net of current portion	5,652	5,401
Deferred tax incentives, net of current portion	417	496
Long-term debt, net of current portion	123,117	106,806
Accrued interest	1,200	1,200
Total liabilities	248,107	260,727
Commitments and contingencies (Note 10)		
Non-controlling interest	273	69
Stockholders' deficit:		
Preferred stock, $0.01 par value: 10,000 shares authorized at June 30, 2015 and December 31, 2014; no shares issued or outstanding at June 30, 2015 or December 31, 2014	—	—
Common stock, $0.01 par value: 200,000 shares authorized at June 30, 2015 and December 31, 2014; 110,798 and 106,697 shares issued and outstanding at June 30, 2015 and December 31, 2014, respectively	1,108	1,067
Additional paid-in capital	567,754	552,037
Accumulated other comprehensive loss	(6)	(74)
Accumulated deficit	(712,193)	(655,170)
Total stockholders' deficit	(143,337)	(102,140)
Total liabilities, non-controlling interest and stockholders' deficit	**$ 105,043**	**$ 158,656**

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 June 30, 2015	Three months ended June 30, 2014	Six months ended June 30, 2015	Six months ended June 30, 2014
Collaboration revenues	$ 36,558	$ 27,815	$ 51,399	$ 40,849
Operating expenses:				
Research and development	42,806	33,795	78,485	64,119
General and administrative	12,315	7,921	21,504	14,145
Total operating expenses	55,121	41,716	99,989	78,264
Loss from operations	(18,563)	(13,901)	(48,590)	(37,415)
Other income and expenses				
Interest income	34	20	80	55
Interest expense	(4,482)	(4,570)	(9,048)	(9,081)
Other, net	110	161	224	397
Net loss	(22,901)	(18,290)	(57,334)	(46,044)
Less net income (loss) attributable to non-controlling interest	(123)	(181)	204	(350)
Net loss attributable to Merrimack Pharmaceuticals, Inc.	$ (22,778)	$ (18,109)	$ (57,538)	$ (45,694)
Other comprehensive income:				
Unrealized gain on available-for-sale securities	21	5	68	21
Other comprehensive income	21	5	68	21
Comprehensive loss	(22,757)	(18,104)	(57,470)	(45,673)
Net loss per share available to common stockholders—basic and diluted	$ (0.21)	$ (0.17)	$ (0.53)	$ (0.44)
Weighted-average common shares used in computing net loss per share available to common stockholders—basic and diluted	109,975	103,809	108,662	103,351

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)	Six months ended June 30, 2015	2014
Cash flows from operating activities		
Net loss	$ (57,334)	$ (46,044)
Adjustments to reconcile net loss to net cash used in operating activities		
Non-cash interest expense	4,038	4,267
Depreciation and amortization	2,092	2,241
Stock-based compensation	8,337	7,091
Changes in operating assets and liabilities		
Purchased premiums and interest on available-for-sale securities	—	(4)
Accounts receivable	1,711	(748)
Accounts payable, accrued expenses and other	7,474	(6,027)
Deferred revenues	(26,502)	(26,169)
Other assets and liabilities, net	527	1,173
Net cash used in operating activities	(59,657)	(64,220)
Cash flows from investing activities		
Purchases of available-for-sale securities	—	(20,100)
Proceeds from maturities of available-for-sale securities	53,963	94,733
Purchases of property and equipment	(4,105)	(2,983)
Net cash provided by investing activities	49,858	71,650
Cash flows from financing activities		
Proceeds from exercise of common stock options and warrants	6,542	4,936
Proceeds from issuance of preferred stock of Silver Creek Pharmaceuticals, Inc.	1,233	—
Proceeds from convertible notes issued by Silver Creek Pharmaceuticals, Inc., net of issuance costs	—	300
Other financing activities, net	—	(1)
Net cash provided by financing activities	7,775	5,235
Net (decrease) increase in cash and cash equivalents	(2,024)	12,665
Cash and cash equivalents, beginning of period	35,688	65,086
Cash and cash equivalents, end of period	$ 33,664	$ 77,751
Non-cash investing and financing activities		
Disposal of fully depreciated assets	106	670
Property and equipment in accounts payable and accrued expenses	2,060	564
Receivables related to stock option exercises	160	—
Supplemental disclosure of cash flows		
Cash paid for interest	$ 4,946	$ 4,915

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

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

1. Nature of the Business

Merrimack Pharmaceuticals, Inc. (the "Company") is a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines consisting of novel therapeutics paired with companion diagnostics for the treatment of cancer. The Company has multiple targeted therapeutic oncology candidates in clinical development. The Company's most advanced program is its investigational agent MM-398. The U.S. Food and Drug Administration (the "FDA") has accepted for review a New Drug Application ("NDA") for MM-398 in combination with 5-fluorouracil ("5-FU") and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy and granted priority review status to the NDA. The FDA has set a goal of October 24, 2015 as the action date for the NDA under the Prescription Drug User Fee Act. In addition, the European Medicines Agency (the "EMA") accepted for review a Marketing Authorization Application ("MAA") filed by Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH (collectively, "Baxalta") for MM-398 in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy. The Company also has multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines. The Company also has an agreement to utilize its manufacturing expertise to develop, manufacture and exclusively supply bulk drug to a third party, who will in turn process the drug into finished product and commercialize it globally. The Company was incorporated in the Commonwealth of Massachusetts in 1993 and reincorporated in the State of Delaware in October 2010.

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

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

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. Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements as of June 30, 2015, and for the three and six months ended June 30, 2015 and 2014, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and generally accepted accounting principles in the United States of America ("GAAP") for condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 filed with the SEC on February 27, 2015.

The information presented in the condensed consolidated financial statements and related notes as of June 30, 2015, and for the three and six months ended June 30, 2015 and 2014, is unaudited. The December 31, 2014 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 six months ended June 30, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015, or any future period.

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

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

During the six months ended June 30, 2015, Silver Creek issued and sold a total of 1.0 million shares of Silver Creek Series B preferred stock at a price per share of $1.35 to investors and received net proceeds of $1.2 million, after deducting issuance costs. The Company's ownership of Silver Creek was 57% and 60% as of June 30, 2015 and December 31, 2014, respectively. The consolidated financial statement activity related to Silver Creek was as follows:

(in thousands)	Non-Controlling Interest
Balance at December 31, 2014	$ 69
Net income attributable to Silver Creek	204
Balance at June 30, 2015	$ 273

(in thousands)	Non-Controlling Interest
Balance at December 31, 2013	$ 337
Net loss attributable to Silver Creek	(350)
Balance at June 30, 2014	$ (13)

3. Net Loss Per Common Share

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

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

For purposes of calculating the maximum dilutive impact, it is presumed that the conversion premium will be settled in common stock, inclusive of a contractual make-whole provision resulting from a fundamental change, and the resulting potential common shares included in diluted earnings per share if the effect is more dilutive. For purposes of this calculation, conversion of the Notes, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. The stock options, warrants and conversion premium on the Notes are excluded from the calculation of diluted loss per share because the net loss for the three and six months ended June 30, 2015 and 2014 causes such securities to be anti-dilutive. The potential dilutive effect of these securities is shown in the chart below:

(in thousands)	As of June 30, 2015	2014
Options to purchase common stock	19,426	21,245
Common stock warrants	377	2,407
Conversion premium on the Notes	25,000	25,000

4. License and Collaboration Agreements

Baxalta

On September 23, 2014, the Company and Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA entered into a license and collaboration agreement (the “Baxalta Agreement”) for the development and commercialization of MM-398 outside of the United States and Taiwan (the “Licensed Territory”). In connection with Baxter International Inc.’s separation of the Baxalta business, the Baxalta Agreement was assigned to Baxalta during the second quarter of 2015. As part of the Baxalta Agreement, the Company granted Baxalta an exclusive, royalty-bearing right and license under the Company’s patent rights and know-how to develop and commercialize MM-398 in the Licensed Territory. Baxalta is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercializing MM-398 in the Licensed Territory. A joint steering committee comprised of an equal number of representatives from each of Baxalta and the Company is responsible for approving changes to the global development plan for MM-398, including all budgets, and overseeing the parties’ development and commercialization activities with respect to MM-398. Unless otherwise agreed, the Company will be responsible for conducting all clinical trials contemplated by the global development plan for MM-398 and manufacturing all clinical material needed for such trials.

Under the terms of the Baxalta Agreement, the Company received a $100.0 million upfront, nonrefundable cash payment in September 2014. In addition, the Company is eligible to receive from Baxalta (i) up to an aggregate of $100.0 million upon the achievement of specified research and

development milestones, of which the Company expects to receive $62.5 million from Baxalta in the second half of 2015, (ii) up to an aggregate of $520.0 million upon the achievement of specified regulatory milestones, of which the Company has received $20.0 million from Baxalta as of June 30, 2015, and (iii) up to an aggregate of $250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxalta Agreement, the Company will bear up to the first $98.8 million of costs related to the development of MM-398 for pancreatic cancer patients who have not previously received gemcitabine-based therapy; however, the Company expects most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. The Company and Baxalta will share equally all other clinical trial costs contemplated by the global development plan. The Company is also entitled to tiered, escalating royalties ranging from sub-teen double-digits to low twenties percentages of net sales of MM-398 in the Licensed Territory.

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

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

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

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

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

The Company has determined that the collaboration represents a services agreement and as such has estimated the level of effort expected to be completed as a result of providing the identified deliverables. The Company will recognize revenue from the nonrefundable upfront payment, forecasted non-substantive milestone payments and estimated payments related to discovery, research, development and technology transfer services based on proportional performance as effort is completed over the expected services period, which is estimated to be substantially complete by December 31, 2019. The Company will periodically review and, if necessary, revise the estimated service period related to its collaboration with Baxalta.

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

During the second quarter of 2015, the EMA accepted for review an MAA filed by Baxalta for MM-398. As a result of this acceptance, the Company recognized $20.0 million of revenue related to a substantive milestone payment owed from Baxalta. During the three and six months ended June 30, 2015, the Company recognized revenue based on the following components of the Baxalta Agreement:

(in thousands)	Three months ended June 30, 2015	Six months ended June 30, 2015
Proportional Performance Model	$ 16,558	$ 31,399
Substantive Milestones	20,000	20,000
Total	$ 36,558	$ 51,399

During the three and six months ended June 30, 2014, the Company recognized no revenue associated with the Baxalta Agreement.

As of June 30, 2015 and December 31, 2014, the Company maintained the following assets and liabilities related to the Baxalta Agreement:

(in thousands)	As of June 30, 2015	As of December 31, 2014
Accounts receivable, billed	$ 807	$ —
Accounts receivable, unbilled	907	1,615
Deferred revenue	$ 64,611	$ 91,156

Of the $64.6 million of deferred revenue related to the Baxalta Agreement, $59.2 million is classified as current in the condensed consolidated balance sheets based upon the Company's estimate of revenue that will be recognized under the proportional performance model as a result of effort expected to be completed within the next twelve months.

Sanofi

On September 30, 2009, the Company and Sanofi entered into a license and collaboration agreement (the "Sanofi Agreement") for the development and commercialization of MM-121. The Sanofi Agreement became effective on November 10, 2009, and Sanofi paid the Company a nonrefundable, noncreditable upfront license fee of $60.0 million. On June 17, 2014, the Company and Sanofi agreed to terminate the Sanofi Agreement effective December 17, 2014. In connection with the agreement to terminate the Sanofi Agreement, among other things, Sanofi transferred ownership of the investigational new drug application for MM-121 back to the Company in July 2014, and the Company waived Sanofi's obligation to reimburse the Company for MM-121 development costs incurred after the effective termination date. Effective upon the termination of the Sanofi Agreement, the Company will not be entitled to receive any additional fees, milestone payments or reimbursements from the collaboration.

The Company received total milestone payments of $25.0 million pursuant to the Sanofi Agreement. Under the Sanofi Agreement, Sanofi was responsible for all MM-121 development and manufacturing costs. Sanofi reimbursed the Company for direct costs incurred in both development and manufacturing and compensated the Company for its internal development efforts based on a full time equivalent rate.

The Company recognized cost reimbursements for MM-121 development services within the period they were incurred and billable. Billable expenses were identified during each specified budget period. In the event that total development services expense incurred and expected to be incurred during the same period exceeded the total contractually allowed billable amount for development services during that period, the Company recognized only a percentage of the development services incurred as revenue during that period.

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

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

During the three and six months ended June 30, 2015, the Company recognized no revenue under the Sanofi Agreement. During the three and six months ended June 30, 2014, the Company recognized revenue based on the following components of the Sanofi Agreement:

(in thousands)	Three months ended June 30, 2014	Six months ended June 30, 2014
Upfront payment	$ 13,268	$ 14,518
Milestone payments	5,529	6,049
Development services	3,040	13,740
Manufacturing services and other	5,978	6,542
Total	$ 27,815	$ 40,849

The Company performed development services for which revenue was recognized under the Sanofi Agreement in accordance with the specified budget period. Additionally, for the six months ended June 30, 2014, there was approximately $5.8 million of increased revenue recognized in the first quarter of 2014, related to the Company receiving budget approval for expenses incurred prior to December 31, 2013.

As of June 30, 2015, the Company maintained no assets or liabilities related to the Sanofi Agreement. As of December 31, 2014, the Company maintained the following assets and liabilities related to the Sanofi Agreement:

(in thousands)	As of December 31, 2014
Accounts receivable, billed	$ 369
Accounts receivable, unbilled	1,282
Deferred revenue	—

PharmaEngine, Inc.

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

On September 22, 2014, the Company amended the PharmaEngine Agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that the Company is required to pay to PharmaEngine. As a result of this amendment, the Company made a $7.0 million milestone payment to PharmaEngine in September 2014. Additionally, as a result of this amendment, a previously contingent $5.0 million milestone payment was paid to PharmaEngine on April 30, 2015. Prior to the amendment of the PharmaEngine Agreement, this milestone payment was contingent upon the award of certain specified regulatory designations. These milestone payments were recognized as research and development expense in September 2014.

As a result of achieving a $20.0 million substantive milestone associated with the Baxalta Agreement during the second quarter of 2015, the Company was required to pay an $11.0 million milestone payment to PharmaEngine. The expense related to this obligation was recorded in the second quarter of 2015 and the payment to PharmaEngine was made in July 2015.

During the three months ended June 30, 2015 and 2014, the Company recognized research and development expenses related to the PharmaEngine Agreement of $11.1 million and $0.1 million, respectively, and during the six months ended June 30, 2015 and 2014, the Company recognized research and development expenses related to the PharmaEngine Agreement of $11.3 million and $0.2 million, respectively.

Actavis

On November 25, 2013, the Company and Watson Laboratories, Inc. ("Actavis") entered into a development, license and supply agreement (the "Actavis Agreement") pursuant to which the Company will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection (the "Initial Product") to Actavis. Under the Actavis Agreement, Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the Actavis Agreement, additional products may be developed for Actavis in the future, the identities of which will be mutually agreed upon. The Company is eligible to receive up to $15.1 million under the Actavis Agreement, of which $3.8 million has been received through June 30, 2015, and the remainder is expected to be received in development funding and development, regulatory and commercial milestone payments related to the Initial Product. The Company will also receive a double digit percentage of net profits on global sales of the Initial Product and any additional products. The Company will manufacture and supply the Initial Product to Actavis in bulk form at an agreed upon unit price.

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

The Company applied revenue recognition guidance to determine whether the performance obligations under this collaboration, including the license, participation on steering committees, development services, and manufacturing and supply services could be accounted for separately or as a single unit of accounting. The Company determined that these obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, the Company has recorded $3.8 million of billed and billable milestones and development expenses related to the Actavis Agreement as deferred revenue as of June 30, 2015 and December 31, 2014, of which $0.1 million is classified as short term as of June 30, 2015 related to revenue the Company expects to recognize in the first half of 2016.

5. Fair Value of Financial Instruments

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

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

Recurring Fair Value Measurements

The following tables show assets and liabilities measured at fair value on a recurring basis as of June 30, 2015 and December 31, 2014 and the input categories associated with those assets and liabilities:

(in thousands) As of June 30, 2015	Level 1	Level 2	Level 3
Assets:			
Cash equivalents – money market funds	$15,187	$ —	$ —
Investments – commercial paper	—	5,000	—
Investments – corporate debt securities	—	28,991	—

As of December 31, 2014	Level 1	Level 2	Level 3
Assets:			
Cash equivalents – money market funds	$33,199	$ —	$ —
Investments – commercial paper	—	6,491	—
Investments – corporate debt securities	—	81,849	—

The Company's investment portfolio consists of investments classified as cash equivalents and available-for-sale securities. All highly liquid investments with an original maturity of three months or less when purchased are considered to be cash equivalents. The Company's cash and cash equivalents are invested in U.S. treasury and various corporate debt securities that approximate their face value. All marketable securities with an original maturity when purchased of greater than three months are classified as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss). The amortized cost of securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. There have been no impairments of the Company's assets measured and carried at fair value during the three and six months ended June 30, 2015. In addition, there were no changes in valuation techniques or transfers between the fair value measurement levels during the three and six months ended June 30, 2015.

Other Fair Value Measurements

The estimated fair value of the $125.0 million aggregate principal amount of the Notes was $261.7 million as of June 30, 2015. The Company estimated the fair value of the Notes by using a quoted market rate in an inactive market, which is classified as a Level 2 input. The carrying value of the Notes is $84.6 million due to the bifurcation of the conversion feature of the Notes as described more fully in Note 7, "Borrowings."

The estimated fair value and carrying value of the loans payable under the Loan Agreement with Hercules was $40.6 million as of June 30, 2015. The Company estimated the fair value of the loans payable by using publically available information related to Hercules' portfolio of debt investments based on unobservable inputs, which is classified as a Level 3 input.

6. Accounts Payable, Accrued Expenses and Other

Accounts payable, accrued expenses and other as of June 30, 2015 and December 31, 2014 consisted of the following:

(in thousands)	As of June 30, 2015	As of December 31, 2014
Accounts payable	$ 6,783	$ 2,510
Accrued goods and services	13,177	12,481
Accrued clinical trial costs	8,514	7,637
Accrued payroll and related benefits	3,866	6,166
Accrued interest	2,944	2,956
Accrued dividends payable	19	19
Accrued milestone payment owed to PharmaEngine	11,000	5,000
Deferred tax incentives	323	467
Total accounts payable, accrued expenses and other	$ 46,626	$ 37,236

7. Borrowings

Future minimum payments under indebtedness agreements outstanding as of June 30, 2015 are as follows:

(in thousands) As of June 30, 2015:	4.50% Convertible Senior Notes	Loan Agreement
Remainder of 2015	$ 2,813	$ 2,157
2016	5,625	13,575
2017	5,625	18,167
2018	5,625	16,639
2019 and thereafter	136,250	—
	155,938	50,538
Less interest	(30,938)	(9,337)
Less unamortized discount	(40,396)	(1,630)
Less current portion	—	(1,058)
Loans payable, net of current portion	$ 84,604	$ 38,513

4.50% Convertible Senior Notes

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

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

The Notes will mature on July 15, 2020 (the “maturity date”), unless earlier repurchased by the Company or converted at the option of holders. Holders may convert their Notes at their option at any time prior to the close of business on the business day immediately preceding April 15, 2020 only under the following circumstances:

- during any calendar quarter commencing after September 30, 2013 (and only during such calendar quarter), if the last reported sale price of the Company’s common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
- during the five business day period after any five consecutive trading day period (the “measurement period”) in which the trading price (as defined in the Notes) per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company’s common stock and the conversion rate on each such trading day; or
- upon the occurrence of specified corporate events set forth in the indenture governing the Notes.

During the second quarter of 2015, the last reported sales price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the calendar quarter ended June 30, 2015 was greater than 130% of the conversion price for the Notes on each applicable trading day. As a result, holders may convert their Notes at their option at any time from July 1, 2015 through September 30, 2015.

On or after April 15, 2020 until the close of business on the business day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances.

Upon any conversion of Notes that occurs while the Company's indebtedness to Hercules under the Loan Agreement remains outstanding, the Notes will be settled in shares of the Company's common stock. Following the repayment and satisfaction in full of the Company's obligations to Hercules under the Loan Agreement, upon any conversion of the Notes, the Notes may be settled, at the Company's election, in cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock.

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

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

For the three and six months ended June 30, 2015, interest expense related to the outstanding principal balance of the Notes was $3.4 million and $6.8 million, respectively. For the three and six months ended June 30, 2014, interest expense related to the outstanding principal balance of the Notes was $3.4 million and $6.8 million, respectively.

Loan Agreement

In November 2012, the Company entered into the Loan Agreement with Hercules pursuant to which the Company received loans in the aggregate principal amount of $40.0 million. The Company, as permitted under the Loan Agreement, had previously extended the interest-only payment period with the aggregate principal balance of the loans to be repaid in monthly installments starting on June 1, 2014 and continuing through November 1, 2016. On June 25, 2014, the Company entered into an amendment to the Loan Agreement, whereby the Company and Hercules agreed to extend until October 1, 2014 the period during which the Company makes interest-only payments. On November 6, 2014, the Company entered into a further amendment to the Loan Agreement, whereby the Company and Hercules agreed to extend by four additional months the period during which the Company makes interest-only payments. On February 25, 2015, the Company entered into a fourth amendment to the Loan Agreement pursuant to which the Company and Hercules agreed to extend the maturity date and the period during which the Company makes interest-only payments on its current term loan in the aggregate principal amount of $40.0 million. As a result of this amendment, the Company will repay the outstanding aggregate principal balance of the term loan beginning on June 1, 2016 and continuing through November 1, 2018. If the FDA approves the Company's NDA for MM-398 by May 1, 2016, the Company may elect to extend the interest-only period by an additional six months so that the Company would repay the outstanding aggregate principal balance of the term loan beginning on December 1, 2016 and continuing through November 1, 2018. In addition, if the FDA approves the Company's NDA for MM-398 by May 1, 2016, the Company may elect to draw, at any time until August 1, 2016, an additional term loan advance of up to $15.0 million. Principal and interest payments on the additional term loan advance would be made in the same manner as the Company's current term loan in the aggregate principal amount of $40.0 million. This amendment was treated as a debt modification for accounting purposes.

Upon the earlier of full repayment of the loans or November 1, 2016, the Company is required to pay Hercules a fee of $1.2 million, which has been recorded as a discount to the loans and as a long-term liability on the Company's condensed consolidated balance sheets. Additionally, the Company reimbursed Hercules for costs incurred related to the loans, which has been reflected as a discount to the carrying value of the loans. The Company is amortizing these loan discounts totaling $1.6 million to interest expense over the term of the loans using the effective interest method. For the three months and six months ended June 30, 2015, interest expense related to Hercules loans payable was $1.2 million and $2.3 million, respectively. For the three and six months ended June 30, 2014, interest expense related to Hercules loans payable was $1.2 million and $2.4 million, respectively.

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

8. Common Stock

As of June 30, 2015 and December 31, 2014, the Company had 200.0 million shares of $0.01 par value common stock authorized. There were approximately 110.8 million and 106.7 million shares of common stock issued and outstanding as of June 30, 2015 and December 31, 2014, respectively.

The shares reserved for future issuance as of June 30, 2015 and December 31, 2014 consisted of the following:

(in thousands)	As of June 30, 2015	As of December 31, 2014
Options to purchase common stock	19,426	19,567
Common stock warrants	377	2,381
Conversion premium on the Notes	25,000	25,000

During the six months ended June 30, 2015, warrants to purchase 2.0 million shares of common stock were exercised in cash and cashless transactions at a weighted average exercise price of $3.00, and 1.5 million shares of common stock were issued. During the six months ended June 30, 2014, warrants to purchase 0.4 million shares of common stock were exercised in cash and cashless transactions at a weighted average exercise price of $3.41, and 0.3 million shares of common stock were issued.

9. Stock-Based Compensation

As of December 31, 2014, there were 2.0 million shares of common stock available to be granted under the Company's 2011 Stock Incentive Plan (the "2011 Plan"). The 2011 Plan is administered by the Company's board of directors and permits the Company to grant incentive and non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards.

In February 2015, 3.7 million additional shares of common stock became available for grant to employees, officers, directors and consultants under the 2011 Plan. During the six months ended June 30, 2015 and 2014, the Company issued options to purchase 2.7 million and 3.1 million shares of common stock, respectively. At June 30, 2015, there were 3.3 million shares remaining available for grant under the 2011 Plan.

The assumptions used to estimate the fair value of options granted to employees and directors at the date of grant for the three and six months ended June 30, 2015 were as follows:

	Three months ended June 30, 2015	Six months ended June 30, 2015
Risk-free interest rate	1.5-1.8%	1.5-1.8%
Expected dividend yield	0%	0%
Expected term	5.0-5.9 years	5.0-5.9 years
Expected volatility	66-67%	66-67%

Options granted to employees generally vest over a three year period. The Company recognized stock-based compensation expense as follows for the three and six months ended June 30, 2015 and 2014:

(in thousands)	Three months ended June 30, 2015	Three months ended June 30, 2014	Six months ended June 30, 2015	Six months ended June 30, 2014
Employee awards:				
Research and development	$ 2,369	$ 1,841	$ 4,335	$ 3,522
General and administrative	2,576	2,161	3,954	3,453
Stock-based compensation for employee awards	4,945	4,002	8,289	6,975
Stock-based compensation for non-employee awards	22	153	48	116
Total stock-based compensation	$ 4,967	$ 4,155	$ 8,337	$ 7,091

The following table summarizes stock option activity during the six months ended June 30, 2015:

(in thousands, except per share amounts and years)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, December 31, 2014	19,556	$ 4.47	6.17	$133,599
Granted	2,723	$ 9.54		
Exercised	(2,595)	$ 2.57		
Forfeited	(258)	$ 6.82		
Outstanding, June 30, 2015	19,426	$ 5.40	6.50	$135,208
Vested and expected to vest, June 30, 2015	19,086	$ 5.36	6.45	$133,696
Exercisable, June 30, 2015	14,210	$ 4.66	5.60	$109,441

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

10. Commitments and Contingencies

Operating Leases

The Company leases its office, laboratory and manufacturing space under non-cancelable operating leases. Total rent expense under these operating leases was $1.9 million and $1.5 million for the three months ended June 30, 2015 and 2014, respectively. Total rent expense under these operating leases was $3.4 million and $3.0 million for the six months ended June 30, 2015 and 2014, respectively.

Other Commitments

In March 2015, the Company received an award of $1.4 million of tax incentives from the Massachusetts Life Sciences Center, which allows the Company to monetize approximately $1.2 million of state research and development tax credits. In exchange for these incentives, the Company pledged to hire an incremental 75 employees and to maintain the additional headcount through at least December 31, 2019. The Company has deferred and will amortize the benefit of the monetization on a straight-line basis over the five-year performance period, commencing with a cumulative catch-up when the pledge is achieved. Failure to achieve this commitment could result in the Company being required to repay some or all of these incentives.

11. Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued guidance which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. This guidance will be effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted for annual periods beginning after December 15, 2016. The Company is currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on the consolidated financial statements.

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

In April 2015, the FASB issued ASU 2015-03, “Interest - Imputation of Interest,” which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This update is effective for annual reporting periods beginning on or after December 15, 2015 and interim periods within fiscal years beginning after December 15, 2016. The Company is currently assessing the impact that adoption of ASU 2015-03 might have on its consolidated financial statements.

12. Subsequent Events

On July 13, 2015, the Company entered into a Sales Agreement with Cowen and Company, LLC (“Cowen”) to sell, from time to time, shares of the Company’s common stock having an aggregate sales price of up to $40,000,000 through an “at the market offering” program under which Cowen will act as sales agent. Through August 7, 2015, the Company has generated approximately $7.7 million in net proceeds under this program.

On July 22, 2015, the Company entered into an amendment to its facility lease. The lease amendment provides an additional 13,843 square feet of leased space at the Company's current facility in Cambridge, Massachusetts, with a termination date of June 30, 2019, which is co-terminous with the Company's existing lease. As a result of this amendment, the Company has additional lease payments totaling approximately $2.2 million through 2019. In addition, under the terms of the amendment, the landlord will provide the Company with an aggregate leasehold improvement allowance of up to approximately $0.5 million.

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, 2014 included in our Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q, which are incorporated herein by reference, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines consisting of novel therapeutics paired with companion diagnostics for the treatment of cancer. We were founded by a team of scientists from The Massachusetts Institute of Technology and Harvard University who sought to develop a systems biology-based approach to biomedical research. The core of our approach to systems biology is to apply multidisciplinary and multitechnology capabilities to build functional and predictive computational models of biological systems, such as cell signaling networks, that allow us to engineer treatments that are directed at the mechanisms of disease. Our mission is to employ these insights to provide patients, physicians and the healthcare system with the medicines, tools and information to deliver integrated healthcare solutions that improve both the quality of outcomes and the efficiency of care. We have multiple targeted therapeutic oncology candidates in clinical development. Our most advanced program is our investigational agent MM-398. The U.S. Food and Drug Administration, or FDA, has accepted for review a New Drug Application, or NDA, for MM-398 in combination with 5-fluorouracil, or 5-FU, and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy and granted priority review status to the NDA. The FDA has set a goal of October 24, 2015 as the action date for the NDA under the Prescription Drug User Fee Act. In addition, the European Medicines Agency, or EMA, accepted for review a Marketing Authorization Application, or MAA, filed by Baxalta for MM-398 in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy. Additionally, we have multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines.

We have devoted substantially all of our resources to our drug discovery and development efforts, including advancing our systems biology approach, conducting clinical trials for our product candidates, protecting our intellectual property, preparing for commercial launch of MM-398 and providing general and administrative support for these operations. We have not generated any revenue from product sales and, to date, have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities and a secured debt financing. Through

June 30, 2015, we have received $268.2 million from the sale of convertible preferred stock and warrants, $126.7 million of net proceeds from the sale of common stock in our April 2012 initial public offering and July 2013 follow-on underwritten public offering, $39.6 million of net proceeds from a secured debt financing, $120.6 million of net proceeds from the issuance of 4.50% convertible senior notes due 2020, or the convertible senior notes, in our July 2013 underwritten public offering and $368.1 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaborations. We have also entered into an arrangement to use our manufacturing capabilities to manufacture drug product on behalf of a third-party pharmaceutical company, for which we have received $3.8 million in upfront fees and reimbursements as of June 30, 2015.

As of June 30, 2015, we had unrestricted cash and cash equivalents and available-for-sale securities of $67.7 million. We expect to be able to fund operations into 2016 through our unrestricted cash and cash equivalents and available-for-sale securities as of June 30, 2015, $51.5 million of milestones related to MM-398 that we anticipate receiving from Baxalta, after offsetting payments to PharmaEngine, and anticipated cost sharing reimbursements from Baxalta.

On July 13, 2015, we entered into a Sales Agreement with Cowen and Company, LLC, or Cowen, to sell, from time to time, shares of our common stock having an aggregate sales price of up to $40,000,000 through an “at the market offering” program under which Cowen will act as sales agent, which we refer to as the ATM Offering. Through August 7, 2015, we have generated approximately $7.7 million in net proceeds in the ATM Offering. Because there is no minimum offering amount required as a condition to close the ATM Offering, the actual total public offering amount is not determinable at this time.

We have never been profitable and, as of June 30, 2015, we had an accumulated deficit of $712.2 million. Our net loss was $22.9 million and $57.3 million for the three and six months ended June 30, 2015, respectively, and $18.3 million and $46.0 million for the three and six months ended June 30, 2014, 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.

Strategic Partnerships, Licenses and Collaborations

Baxalta

On September 23, 2014, we entered into a license and collaboration agreement with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, which we refer to as the Baxalta agreement, for the development and commercialization of MM-398 outside of the United States and Taiwan, or the licensed territory. In connection with Baxter International Inc.’s separation of the Baxalta business, the Baxalta Agreement was assigned to Baxalta during the second quarter of 2015. As part of the Baxalta agreement, we granted Baxalta an exclusive, royalty-bearing right and license under

our patent rights and know-how to develop and commercialize MM-398 in the licensed territory. Baxalta is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercialize MM-398 in the licensed territory. A joint steering committee comprised of an equal number of representatives from each of Baxalta and us is responsible for approving changes to the global development plan for MM-398, including all budgets, and overseeing the parties' development and commercialization activities with respect to MM-398. Unless otherwise agreed, we will be responsible for conducting all clinical trials contemplated by the global development plan for MM-398.

Under the terms of the Baxalta agreement, we received a $100.0 million upfront, nonrefundable cash payment in September 2014. In addition, we are eligible to receive from Baxalta (i) up to an aggregate of $100.0 million upon the achievement of specified research and development milestones, of which we expect to receive $62.5 million from Baxalta in the second half of 2015, (ii) up to an aggregate of $520.0 million upon the achievement of specified regulatory milestones, of which we have received $20.0 million from Baxalta as of June 30, 2015, and (iii) up to an aggregate of $250.0 million upon the achievement of specified sales milestones. Under the terms of the Baxalta agreement, we will bear up to the first $98.8 million of costs related to the development of MM-398 for pancreatic cancer patients who have not previously received gemcitabine-based therapy; however, we expect most of these costs to be offset by payments received upon the achievement of clinical trial-related milestones. We will share equally with Baxalta all other clinical trial costs contemplated by the global development plan. We are also entitled to tiered, escalating royalties ranging from sub-teen double-digits to low twenties percentages of net sales of MM-398 in the licensed territory.

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

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

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

At the inception of the collaboration, we identified the following deliverables as part of the Baxalta agreement: (i) license to develop and commercialize MM-398 in Baxalta's territories, (ii)

discovery, research, development and manufacturing services required to complete ongoing clinical trials related to MM-398, (iii) discovery, research, development and manufacturing services needed to complete future clinical trials in further indications related to MM-398, (iv) the option to perform a technology transfer of our manufacturing process related to the production of MM-398 to Baxalta and (v) participation on the joint steering committee.

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

We have determined that the collaboration represents a services agreement and as such have estimated the level of effort expected to be completed as a result of providing the identified deliverables. We will recognize revenue from the nonrefundable upfront payment, forecasted non-substantive milestone payments and estimated payments related to discovery, research, development and technology transfer services based on proportional performance as effort is completed over the expected services period, which is estimated to be substantially complete by December 31, 2019. We will periodically review and, if necessary, revise the estimated service period related to our collaboration with Baxalta.

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

During the second quarter of 2015, the EMA accepted for review an MAA filed by Baxalta for MM-398. As a result of this acceptance, we recognized $20.0 million of revenue related to a substantive milestone payment owed from Baxalta. During the three and six months ended June 30, 2015, we recognized revenue based on the following components of the Baxalta Agreement:

(in thousands)	Three months ended June 30, 2015	Six months ended June 30, 2015
Proportional performance model	$ 16,558	$ 31,399
Substantive milestones	20,000	20,000
Total	$ 36,558	$ 51,399

As of June 30, 2015 and December 31, 2014, we maintained the following assets and liabilities related to the Baxalta agreement:

(in thousands)	As of June 30, 2015	As of December 31, 2014
Accounts receivable, billed	$ 807	$ —
Accounts receivable, unbilled	907	1,615
Deferred revenue	64,611	91,156

Of the $64.6 million of deferred revenue related to the Baxalta agreement, $59.2 million is classified as current in the consolidated balance sheets based upon our estimate of revenue that will be recognized under the proportional performance model as a result of effort expected to be completed within the next twelve months.

Sanofi

In September 2009, we entered into a license and collaboration agreement with Sanofi, which we refer to as the Sanofi agreement, for the development and commercialization of MM-121. On June 17, 2014, we agreed with Sanofi to terminate the Sanofi agreement effective December 17, 2014. In connection with the agreement to terminate the Sanofi agreement, among other things, Sanofi transferred ownership of the investigational new drug application for MM-121 back to us in July 2014, and we have waived Sanofi's obligation to reimburse us for MM-121 development costs incurred after the effective termination date. Effective upon the termination of the Sanofi agreement, we will not be entitled to receive any additional fees, milestone payments or reimbursements from the collaboration.

Through June 30, 2015, Sanofi had paid us a nonrefundable, noncreditable upfront license fee of $60.0 million, as well as additional aggregate milestone payments of $25.0 million. Under the Sanofi agreement, Sanofi was responsible for all MM-121 development and manufacturing costs. Sanofi reimbursed us for internal time at a designated full-time equivalent rate per year and reimbursed us for direct costs and services related to the development and manufacturing of MM-121.

We recognized cost reimbursements for MM-121 development services within the period they were incurred and billable. Billable expenses were defined during each specified budget period. In the event that total development services expense incurred and expected to be incurred during any particular budget period exceeded the total contractually allowed billable amount for development services during that period, we recognized only a percentage of the development services incurred as revenue during that period.

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

As a result of the agreement to terminate the Sanofi agreement, the development period was revised to end as of December 17, 2014 and the balance of deferred revenue remaining as of April 1, 2014 was recognized prospectively on a straight-line basis over the remaining development period, ending on December 17, 2014. During the three and six months ended June 30, 2015, we recognized no revenue associated with the Sanofi agreement due to its termination effective December 17, 2014. During the three and six months ended June 30, 2014, we recognized revenue based on the following components of the Sanofi agreement:

(in thousands)	Three months ended June 30, 2014	Six months ended June 30, 2014
Upfront payment	$ 13,268	$ 14,518
Milestone payments	5,529	6,049
Development services	3,040	13,740
Manufacturing services and other	5,978	6,542
Total	$ 27,815	$ 40,849

Actavis

In November 2013, we entered into a development, license and supply agreement with Watson Laboratories, Inc., or Actavis, which we refer to as the Actavis agreement, pursuant to which we will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection, or the initial product, to Actavis. Under the Actavis agreement, Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the Actavis agreement, we have also agreed to develop additional products for Actavis in the future, the identities of which will be mutually agreed upon. We are eligible to receive up to $15.1 million, of which $3.8 million has been received through June 30, 2015, and the remainder is expected to be received in development funding and development, regulatory and commercial milestone payments related to the initial product. We will also receive a double digit percentage of net profits on global sales of the initial product and any additional products. We will manufacture and supply the initial product to Actavis in bulk form at an agreed upon unit price.

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

We applied revenue recognition guidance to determine whether the performance obligations under this collaboration, including the license, participation on steering committees, development services, and manufacturing and supply services, could be accounted for separately or as a single unit of accounting. We determined that these obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, we have recorded $3.8 million of total billed and billable milestones and development expenses related to the Actavis agreement as deferred revenue as of June 30, 2015 and December 31, 2014, of which $0.1 million is classified as short term as of June 30, 2015 related to revenue we expect to recognize in the first half of 2016.

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, under which PharmaEngine received an exclusive license to research, develop, manufacture and commercialize MM-398 in Europe and certain countries in Asia. In May 2011, we entered into a new agreement with PharmaEngine, which we refer to as the PharmaEngine agreement, under which we reacquired all previously licensed rights for MM-398, other than rights to commercialize MM-398 in Taiwan. As a result, prior to entering into the Baxalta agreement, we had 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.

On September 22, 2014, we amended the PharmaEngine agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that we are required to pay to PharmaEngine. As a result of this amendment, we made a $7.0 million milestone payment to PharmaEngine. Additionally, as a result of this amendment, a previously contingent $5.0 million milestone payment was paid to PharmaEngine on April 30, 2015. Prior to the amendment of the PharmaEngine agreement, this milestone payment was contingent upon the award of certain specified regulatory designations. These milestone payments were recognized as research and development expense during September 2014.

Since entering into the PharmaEngine agreement, we have paid PharmaEngine an aggregate of $38.0 million in upfront license fees and milestone payments, including an $11.0 million milestone

payment made in July 2015 in connection with the EMA's acceptance for review of an MAA for MM-398, which occurred, and was recognized as research and development expense, in the second quarter of 2015. In addition to these amounts, we will also be required to pay PharmaEngine up to an additional $60.0 million in aggregate regulatory milestones, $3.5 million in sublicense fees and $130.0 million in aggregate sales milestones, in each case with respect to Europe and certain countries in Asia. PharmaEngine is also entitled to tiered royalties on net sales of MM-398 in Europe and certain countries in Asia. The royalty rates under the PharmaEngine agreement range from high single digits up to the low teens as a percentage of our net sales of MM-398 in these territories. Under the PharmaEngine agreement, we are responsible for all future development costs of MM-398 except those required specifically for regulatory approval in Taiwan. During the three months ended June 30, 2015 and 2014, we recognized research and development expenses of $11.1 million and $0.1 million, respectively. During the six months ended June 30, 2015 and 2014, we recognized research and development expenses of $11.3 million and $0.2 million, respectively.

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

Financial Operations Overview

Revenues

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

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research, development and manufacturing efforts and 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 prior to the fourth quarter of 2015, if at all. If we or our collaborators fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

We expect that revenues in 2015 under the Baxalta agreement will exceed revenues in 2014, as we will have performed a full year of services under the Baxalta agreement. As a result, we expect to recognize additional revenue under our proportional performance model. Additionally, we have achieved a $20.0 million substantive regulatory milestone in the second quarter of 2015 related to the EMA's acceptance for review of an MAA for MM-398, which occurred in the second quarter of 2015. We do not expect there to be an increase in revenue related to the $62.5 million of research and development milestones expected to be achieved under the Baxalta agreement in the second half of 2015, as they are considered non-substantive, and as such will be included in our proportional performance model.

We do not expect to record any revenues under the Sanofi agreement in 2015 due to the termination of the Sanofi agreement effective December 17, 2014.

Research and development expense

Research and development expenses consist of the costs associated with our research and discovery activities, including investment in our systems biology approach, conduct of preclinical studies

and clinical trials, manufacturing development efforts and activities related to regulatory filings. Our research and development expenses consist of:

- employee salaries and related expenses, which include stock compensation and benefits for the personnel involved in our drug discovery and development activities;
- external research and development expenses incurred under agreements with third-party contract research organizations and investigative sites;
- manufacturing material expense for in-house manufacturing and third-party manufacturing organizations and consultants, including costs associated with manufacturing product prior to regulatory approval;
- license fees for and milestone payments related to in-licensed products and technologies; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory and other supplies.

We expense research and development costs as incurred. Conducting a significant amount of research and development is central to our business model. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late stage clinical trials. We expect to maintain or increase our research and development expenses for the foreseeable future as we continue to develop our clinical stage product candidates and further advance our preclinical products and earlier stage research and development projects.

We use our employee and infrastructure resources across multiple research and development programs. We track expenses related to our clinical stage product candidates on a per project basis. Accordingly, we allocate internal employee-related and infrastructure costs, as well as third-party costs, to each of these programs. We do not allocate to particular development programs either stock compensation expense or expenses related to preclinical programs. Costs that are not directly attributable to specific clinical programs or early preclinical activities, such as wages related to shared laboratory services, travel and employee training and development, are not allocated and are considered general research and discovery expenses.

The following table summarizes our principal product development programs, including the research and development expenses allocated to each clinical product candidate.

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2015	2014	2015	2014
MM-398	$15,543	$ 4,929	$24,527	$ 9,914
MM-302	3,736	3,945	8,675	7,702
MM-121	1,432	2,750	3,626	4,648
MM-141	3,276	3,262	6,909	5,578
MM-111	676	5,071	3,141	8,470
MM-151	1,246	2,300	2,434	6,407
Preclinical, general research and discovery	14,530	9,697	24,836	17,878
Stock compensation	2,369	1,841	4,338	3,522
Total research and development expense	$42,806	$33,795	$78,485	$64,119

The development, regulatory and clinical expenses related to the Actavis agreement are included within our preclinical, general research and discovery expenses.

MM-398

The FDA has accepted for review our NDA for MM-398 in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy and granted priority review status to the NDA. The FDA has set a goal of October 24, 2015 as the action date for the NDA under the Prescription Drug User Fee Act. In addition, the EMA accepted for review an MAA filed by Baxalta for MM-398 in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy. We recently expanded a Phase 1 translational clinical study in patients with solid tumors to identify predictive imaging biomarkers associated with MM-398 for the purpose of estimating drug delivery to the tumor and patient response. In addition, we are also collaborating with several investigators to conduct additional trials of MM-398, including an investigator-sponsored Phase 1 clinical trial utilizing a high concentration formulation of MM-398 in patients with glioma and an investigator-initiated Phase 1 clinical trial in patients with pediatric solid tumors, which is being conducted under our investigational new drug application. Additionally, we anticipate initiating additional clinical trials of MM-398 in front-line pancreatic cancer and gastric cancer.

In the third quarter of 2014, we made a milestone payment of $7.0 million to PharmaEngine in connection with entering into the Baxalta agreement. As a result of the amendment of the PharmaEngine agreement in September 2014, a previously contingent $5.0 million milestone payment was recognized as research and development expense during the third quarter of 2014 and was paid to PharmaEngine on April 30, 2015. We are not obligated to make any other milestone payments to PharmaEngine with respect to regulatory submissions or approvals in the United States. During the second quarter of 2015, we recognized $11.0 million of research and development expense as a result of the EMA's acceptance for review of an MAA for MM-398. This $11.0 million milestone payment was paid to PharmaEngine in July 2015. We will also be required to pay PharmaEngine up to an additional $60.0 million in aggregate regulatory milestones, $3.5 million in sublicense fees and $130.0 million in aggregate sales milestones, in each case with respect to Europe and certain countries in Asia. PharmaEngine is also entitled to tiered royalties based on net sales of MM-398 in Europe and certain countries in Asia. The royalty rates range from high single digits up to the low teens as a percentage of net sales of MM-398 in these territories.

MM-302

We are currently conducting one Phase 1 clinical trial and a Phase 2 clinical trial of MM-302 in breast cancer, which was initiated in August 2014.

MM-121

In September 2009, we entered into the Sanofi agreement related to MM-121. On June 17, 2014, we agreed with Sanofi that the Sanofi agreement would terminate effective December 17, 2014. Under the terms of the agreement, we were responsible for executing clinical trials through the development period that ended December 17, 2014. We separately recorded revenue and expenses on a gross basis under this arrangement. Sanofi remained responsible for all development and manufacturing costs of MM-121 through December 17, 2014, subsequent to which we became fully responsible for development and manufacturing costs of MM-121. We are currently completing close out activities for four Phase 2 clinical trials and three Phase 1 clinical trials of MM-121 in multiple cancer types. In February 2015, we initiated a Phase 2 clinical trial in non-small cell lung cancer.

MM-141

We are currently conducting a Phase 1 clinical trial of MM-141 in solid tumors and a Phase 2 clinical trial of MM-141 in front-line pancreatic cancer, which was initiated in May 2015. The Phase 2 clinical trial is expected to enroll 146 front-line metastatic pancreatic cancer patients who have high serum levels of free IGF-1 in a randomized (1:1), double-blinded, placebo-controlled trial. The primary endpoint of the trial is progression free survival. Secondary endpoints include overall survival, objective response rate, safety and tolerability.

MM-111

We are currently concluding a Phase 2 clinical trial of MM-111 in gastric, esophageal and gastroesophageal cancers. In February 2015, we stopped enrolling patients in this clinical trial prior to full enrollment based on a recommendation from the Data Safety Monitoring Board for the clinical trial, which cited shorter progression free survival on the treatment arm relative to the control arm in the overall patient population. We do not expect to enroll any new patients in this clinical trial and do not plan to invest in additional development of MM-111 at this time.

MM-151

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

General and administrative expense

General and administrative expense consists primarily of salaries and other related costs for personnel, including stock-based compensation expenses and benefits, in our legal, intellectual property, business development, pre-commercial, finance, information technology, corporate communications, investor relations and human resources departments. Other general and administrative expenses include employee training and development, board of directors costs, depreciation, insurance expenses, facility-related costs not otherwise included in research and development expense, professional fees for legal services, including patent-related expenses, pre-commercialization costs, and accounting and information technology services. We expect that general and administrative expense will increase in future periods in proportion to increases in research and development and as a result of increased payroll, expanded infrastructure, increased consulting, legal, accounting and investor relations expenses associated with being a public company and costs incurred to develop and commercialize our clinical products. In addition, we expect that general and administrative expense will increase significantly if we receive FDA approval of our NDA for MM-398 as we initiate commercialization activities.

Interest expense

Interest expense consists primarily of cash and non-cash interest recorded on our loans payable and convertible senior notes. We expect that interest expense in 2015 will be comparable with 2014, continuing through the time periods that our loans payable and convertible senior notes remain outstanding.

Other income

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with the rules and regulations of the Securities and Exchange Commission, or the SEC, and generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Estimates include revenue recognition, lease accounting, valuation of derivative liabilities and embedded conversion options, useful lives with respect to long-lived assets and intangibles, valuation of stock options, convertible preferred stock warrants, contingencies, accrued expenses, including clinical research cost accruals, and other, intangible assets, goodwill, in-process research and development and tax valuation reserves. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

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

Our critical accounting policies and the methodologies and assumptions we apply under them have not materially changed since February 27, 2015, the date we filed our Annual Report on Form 10-K for the year ended December 31, 2014. For more information on our critical accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2014.

Results of Operations

Comparison of the three months ended June 30, 2015 and 2014

(in thousands)	Three months ended June 30, 2015	2014
Collaboration revenues	$ 36,558	$ 27,815
Research and development expenses	42,806	33,795
General and administrative expenses	12,315	7,921
Loss from operations	(18,563)	(13,901)
Interest income	34	20
Interest expense	(4,482)	(4,570)
Other income	110	161
Net loss	$(22,901)	$(18,290)

Collaboration revenues

Collaboration revenues for the three months ended June 30, 2015 were $36.6 million, compared to $27.8 million for the three months ended June 30, 2014, an increase of $8.7 million, or 31%. This increase was primarily attributable to revenue related to the Baxalta agreement that we entered into during the third quarter of 2014, including $20.0 million of substantive milestone revenue recognized during the second quarter of 2015. This increase was offset by $27.8 million of decreased revenue related to the Sanofi agreement, which was terminated effective December 17, 2014.

Research and development expenses

Research and development expenses for the three months ended June 30, 2015 were $42.8 million, compared to $33.8 million for the three months ended June 30, 2014, an increase of $9.0 million, or 27%. This increase was primarily attributable to $10.6 million of increased MM-398 expenses primarily due to costs associated with the $11.0 million of milestone payments owed to PharmaEngine as of June 30, 2015. Additional increases were due to $4.8 million of increase preclinical, general research and discovery expenses due to additional preclinical trials ongoing as well as the timing of material purchases for manufacturing runs.

This increase was partially offset by:

- $4.4 million of decreased expenses primarily due to the decision to stop enrolling patients in the MM-111 trial;
- $1.3 million of decreased MM-121 expenses primarily due to costs associated with analyzing and concluding ongoing and completed clinical trials; and
- $1.1 million of decreased MM-151 expenses primarily due to the timing of costs associated with our ongoing clinical trial, diagnostic efforts and a manufacturing campaign.

General and administrative expenses

General and administrative expenses for the three months ended June 30, 2015 were $12.3 million, compared to $7.9 million for the three months ended June 30, 2014, an increase of $4.4 million, or 55%. This increase was primarily attributable to increases in labor and labor-related costs, efforts to prepare for commercialization of our product candidates and increased facility-related costs.

Interest expense

Interest expense for the three months ended June 30, 2015 was $4.5 million, compared to $4.6 million for the three months ended June 30, 2014.

Comparison of the six months ended June 30, 2015 and 2014

	Six months ended June 30,	
(in thousands)	**2015**	**2014**
Collaboration revenues	$ 51,399	$ 40,849
Research and development expenses	78,485	64,119
General and administrative expenses	21,504	14,145
Loss from operations	(48,590)	(37,415)
Interest income	80	55
Interest expense	(9,048)	(9,081)
Other income	224	397
Net loss	$(57,334)	$(46,044)

Collaboration revenues

Collaboration revenues for the six months ended June 30, 2015 were $51.4 million, compared to $40.8 million for the six months ended June 30, 2014, an increase of $10.6 million, or 26%. This increase was primarily attributable to revenue related to the Baxalta agreement that we entered into during the third quarter of 2014, including $20.0 million of substantive milestone revenue recognized during the second quarter of 2015. This increase was offset by $40.8 million of decreased revenue related to the Sanofi agreement, which was terminated effective December 17, 2014.

Research and development expenses

Research and development expenses for the six months ended June 30, 2015 were $78.5 million, compared to $64.1 million for the six months ended June 30, 2014, an increase of $14.4 million, or 22%. This increase was primarily attributable to:

- $14.6 million of increased MM-398 expenses primarily due to $11.0 million of milestone payments earned by PharmaEngine during the second quarter of 2015 and ongoing clinical trials;
- $7.0 million of increased expenses related to 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, as well as increases due to the timing of material purchases for manufacturing runs; and
- $1.3 million of increased expenses related to an ongoing clinical trial and diagnostic efforts related to MM-141.

These increases were partially offset by:

- $5.3 million of decreased MM-111 expenses primarily due to the decision to stop enrolling patients;
- $4.0 million of decreased MM-151 expenses primarily due to the timing of costs associated with our ongoing clinical trial, diagnostic efforts and a manufacturing campaign; and
- $1.0 million of decreased MM-121 expenses primarily due to costs associated with analyzing and concluding ongoing and completed clinical trials.

General and administrative expenses

General and administrative expenses for the six months ended June 30, 2015 were $21.5 million, compared to $14.1 million for the six months ended June 30, 2014, an increase of $7.4 million, or 52%. This increase was primarily attributable to increases in labor and labor-related costs, efforts to prepare for commercialization of our product candidates and increased facility-related costs.

Interest expense

Interest expense for the six months ended June 30, 2015 was $9.0 million, compared to $9.1 million for the six months ended June 30, 2014.

Liquidity and Capital Resources

Sources of liquidity

We have financed our operations to date primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities and a secured debt financing. Through June 30, 2015, we have received $268.2 million from the sale of convertible preferred stock and warrants, $126.7 million of net proceeds from the sale of common stock in our initial public offering and July 2013 follow-on underwritten public offering, $39.6 million of net proceeds from a secured debt financing, $120.6 million of net proceeds from the issuance of the convertible senior notes in our July 2013 underwritten public offering, and $368.1 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from

our collaborations. We have also entered into an arrangement to use our manufacturing capabilities to manufacture drug product on behalf of Actavis, for which we have received $3.8 million in upfront fees and reimbursements as of June 30, 2015. As of June 30, 2015, we had unrestricted cash and cash equivalents and available-for-sale securities of $67.7 million.

As of June 30, 2015, within our unrestricted cash and cash equivalents, $1.4 million was cash and cash equivalents held by our majority owned subsidiary, Silver Creek Pharmaceuticals, Inc., or Silver Creek, which is consolidated for financial reporting purposes. This $1.4 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 six months ended June 30, 2015 and 2014.

	Six months ended June 30,	
(in thousands)	**2015**	**2014**
Cash used in operating activities	$(59,657)	$(64,220)
Cash provided by investing activities	49,858	71,650
Cash provided by financing activities	7,775	5,235
Net (decrease) increase in cash and cash equivalents	$ (2,024)	$ 12,665

Operating activities

Cash used in operating activities of $59.7 million during the six months ended June 30, 2015 was primarily a result of our net loss of $57.3 million as well as a decrease in deferred revenue due to the recognition of revenue under the proportional performance model associated with the Baxalta agreement. These changes were partially offset by an increase in accounts payable and stock-based compensation charges, as well as by other changes in operating assets and liabilities. Cash used in operating activities of $64.2 million during the six months ended June 30, 2014 was primarily a result of our net loss of $46.0 million and changes in operating assets and liabilities of $31.8 million, which includes $22.5 million of deferred revenue recognition attributable to the reassessment of the development period with Sanofi, which ended effective December 17, 2014, partially offset by non-cash items of $13.6 million.

Investing activities

Cash provided by investing activities of $49.9 million during the six months ended June 30, 2015 was primarily due to the maturities of marketable securities of $54.0 million, partially offset by $4.1 million of purchases of property and equipment. Cash provided by investing activities during the six months ended June 30, 2014 was primarily due to the maturity of marketable securities of $94.7 million, which was partially offset by purchases of marketable securities of $20.1 million, as well as $3.0 million related to the purchase of property and equipment.

Financing activities

Cash provided by financing activities of $7.8 million during the six months ended June 30, 2015 was primarily a result of $6.5 million of proceeds from the issuance of common stock related to stock option and common stock warrant exercises as well as $1.2 million of proceeds from the issuance of Series B preferred stock by Silver Creek. Cash provided by financing activities during the six months

ended June 30, 2014 was primarily a result of proceeds from the issuance of common stock related to stock option and common stock warrant exercises as well as $0.3 million of proceeds from the sale and issuance of convertible notes by Silver Creek.

Borrowings and other liabilities

We have convertible debt outstanding as of June 30, 2015 related to our 4.50% convertible senior notes due 2020, which we issued in July 2013 in the aggregate principal amount of $125.0 million. The convertible senior notes are convertible into common stock upon satisfaction of certain conditions. The convertible senior notes bear interest at a fixed rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year. The convertible senior notes will mature on July 15, 2020 unless earlier repurchased by us or converted at the option of holders. See Note 7, “Borrowings,” in the accompanying notes to condensed consolidated financial statements for additional information.

In November 2012, we entered into a $40.0 million Loan and Security Agreement, or loan agreement, with Hercules Technology Growth Capital, Inc., or Hercules, which, as amended, provides for interest-only payments until June 1, 2016. Beginning on June 1, 2016, the aggregate outstanding principal balance of the loans is due in equal monthly installments of principal and interest, with the remaining principal balance and interest due and payable on November 1, 2018. An additional $1.2 million is due to Hercules upon the earlier of full repayment of the loans or November 1, 2016, which amount has been recorded as a discount to the loans and as a long-term liability on our condensed consolidated balance sheets. See Note 7, “Borrowings,” in the accompanying notes to condensed consolidated financial statements for additional information.

Funding requirements

We have not completed development of any therapeutic products or companion diagnostics, although the FDA has accepted for review an NDA for MM-398 in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy and granted priority review status to the NDA. 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 clinical stage product candidates;
- continue the research and development of our other product candidates;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials, including MM-398 in combination with 5-FU and leucovorin;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize products for which we may seek regulatory approval, including MM-398 in combination with 5-FU and leucovorin; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned commercialization efforts.

As of June 30, 2015, we had unrestricted cash and cash equivalents and available-for-sale securities of $67.7 million. We expect to be able to fund operations into 2016 through our unrestricted cash and cash equivalents and available-for-sale securities as of June 30, 2015, $51.5 million of net milestones related to MM-398 that we anticipate receiving from Baxalta in 2015, after offsetting payments to PharmaEngine, and anticipated cost sharing reimbursements from Baxalta. The $51.5 million

of anticipated net milestones includes a one-time $15.0 million research and development milestone payment owed from Baxalta to us 45 days following the submission to the FDA of the protocol for a clinical study of MM-398 in front-line pancreatic cancer, during which period there is no notification of a clinical hold from the FDA. This submission to the FDA occurred on June 30, 2015. Also included in the $51.5 million is a $47.5 million research and development milestone payment owed from Baxalta to us if a patient is dosed in a clinical trial of MM-398 in front-line pancreatic cancer. We expect both of these milestones to be met in the second half of 2015. These milestone payments are offset by an $11.0 million milestone payment owed to PharmaEngine related to the EMA's acceptance for review of an MAA for MM-398. This acceptance was received during the second quarter of 2015, and this payment was made in July 2015.

We have based the funding requirement 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 clinical stage product candidates;
- the success of our collaborations with Baxalta and PharmaEngine related to MM-398 and any future collaborations with other parties that we may enter into;
- the timing and amount of anticipated milestone payments and cost sharing reimbursements related to MM-398 that we may receive from Baxalta;
- 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, including our NDA for MM-398;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products and technologies;
- our ability to establish and maintain commercial manufacturing arrangements for the manufacture of drug product on behalf of third-party pharmaceutical companies; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external sources of funds, other than our collaboration with Baxalta for the development and commercialization of MM-398, which is terminable by Baxalta for convenience upon 180 days' prior written notice, and under our development, license and supply agreement with Actavis, which is

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

Contractual obligations and commitments

In March 2015, we received an award of $1.4 million of tax incentives from the Massachusetts Life Sciences Center, which allows us to monetize approximately $1.2 million of state research and development tax credits. In exchange for these incentives, we pledged to hire an incremental 75 employees and to maintain the additional headcount through at least December 31, 2019. Income related to this award will not be recognized until the pledged headcount has been achieved. Failure to achieve this commitment could result in us being required to repay some or all of these incentives.

As of June 30, 2015, there were no other material changes to our contractual obligations and commitments outside the ordinary course of business.

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued guidance which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. This guidance will be effective for fiscal years, and interim periods within those years, beginning after December 15, 2017, and early adoption is permitted for annual periods beginning after December 15, 2016. We are currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on our consolidated financial statements.

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

In April 2015, the FASB issued ASU 2015-03, "Interest - Imputation of Interest," which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This update is effective for annual reporting periods beginning on or after December 15, 2015 and interim periods within fiscal years beginning after December 15, 2016. We are currently assessing the impact that adoption of ASU 2015-03 might have on our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates, particularly because our investments are in short-term marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability and intention to hold our investments until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

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

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

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2015. 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 June 30, 2015, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended June 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

Item 1A. Risk Factors.

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 1 of this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

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

Since inception, we have incurred significant operating losses. Our net loss was $56.1 million for the six months ended June 30, 2015, $83.6 million for the year ended December 31, 2014 and $130.7 million for the year ended December 31, 2013. As of June 30, 2015, we had an accumulated deficit of $711.0 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities and a secured debt financing. We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed development of or commercialized any therapeutic product candidates or companion diagnostics. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

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

To become and remain profitable, we must succeed in developing and eventually commercializing products with significant market potential. This will require us to be successful in a range of challenging activities, including discovering product candidates, completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling those products for which we may seek regulatory approval. We are only in the preliminary stages of some of these activities. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could

impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

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

We currently have, and will continue to have, a significant amount of indebtedness. As of June 30, 2015, we had outstanding borrowings in an aggregate principal amount of $40.0 million under the loan agreement with Hercules. In addition, on July 17, 2013, we issued $125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020. We could in the future incur additional indebtedness beyond such amounts.

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

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

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

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents and available-for-sale securities and funds from external sources. However, we may not have sufficient funds or may be unable to arrange for additional financing to pay the amounts due under our existing debt. Funds from external sources may not be available on acceptable terms, if at all. In addition, a failure to comply with the covenants under our existing debt instruments could result in an event of default under those instruments. In the event of an acceleration of amounts due under our debt instruments as a result of an event of default, including upon the occurrence of an event that would reasonably be expected to have a material adverse effect on our business, operations, properties, assets or condition or a failure to pay any amount due, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness. In addition, the covenants under our existing debt instruments and the pledge of our assets as collateral limit our ability to obtain additional debt financing.

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

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

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

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

We expect to be able to fund operations into 2016 through our unrestricted cash and cash equivalents and available-for-sale securities of $67.7 million as of June 30, 2015, $51.5 million of net milestones related to MM-398 that we anticipate receiving from Baxalta in 2015, after offsetting payments to PharmaEngine, and anticipated cost sharing reimbursements from Baxalta. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our clinical stage product candidates;
- the success of our collaborations with Baxalta and PharmaEngine related to MM-398 and any future collaborations with other parties that we may enter into;
- the timing and amount of anticipated milestone payments and cost sharing reimbursements related to MM-398 that we may receive from Baxalta;
- 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, including our NDA for MM-398;
- the costs of commercialization activities, including product sales, marketing, manufacturing and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products and technologies;

- our ability to establish and maintain commercial manufacturing arrangements for the manufacture of drug product on behalf of third-party pharmaceutical companies; and
- our ability to establish and maintain additional collaborations on favorable terms, particularly marketing and distribution arrangements for oncology product candidates.

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external source of funds, other than under our collaboration with Baxalta for the development and commercialization of MM-398, which is terminable by Baxalta for convenience upon 180 days' prior written notice, and under our development, license and supply agreement with Actavis, which is terminable by Actavis for convenience in specified circumstances upon 90 days' prior written notice. Other sources of funds may not be available or, if available, may not be available on terms satisfactory to us and could result in significant stockholder dilution.

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

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

We invest our cash in a variety of financial instruments, principally securities issued by the U.S. government and its agencies, investment grade corporate bonds, including commercial paper, and money market instruments. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may

have a material adverse effect on our business, results of operations, liquidity and financial condition. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities.

Risks Related to the Development and Commercialization of Our Product Candidates

We depend heavily on the success of our clinical stage 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 other clinical stage 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 prior to the fourth quarter of 2015, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates. The success of our product candidates, which include both our therapeutic product candidates and companion diagnostic candidates, will depend on several factors, including the following:

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

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

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

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and successful interim results of a clinical trial do not necessarily predict successful final results.

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

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

For example, in February 2015, we stopped enrolling patients in our Phase 2 clinical trial of MM-111 for the treatment of advanced gastric, esophageal and gastroesophageal junction cancers prior to full enrollment based on a recommendation from the Data Safety Monitoring Board for the clinical trial, which cited shorter progression free survival on the treatment arm relative to the control arm in the overall patient population. We do not expect to enroll any new patients in this clinical trial and do not plan to invest in additional development of MM-111 at this time. In our Phase 2 clinical trial of MM-121 in patients with non-small cell lung cancer, two of the three cohorts (Groups A and C) failed to meet their primary endpoints, and the third cohort (Group B) did not pass its planned interim analysis and ceased enrolling patients. Additionally, we did not meet the primary endpoints in our Phase 2 clinical trials of MM-121 in patients with ovarian cancer or in patients with breast cancer, although our ongoing biomarker analysis in each trial identified a potential subpopulation of patients benefiting from MM-121 in combination with either paclitaxel or exemestane, respectively.

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

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

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

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

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

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

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

All of our product candidates are still in preclinical or clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. Currently marketed therapies for solid tumors are generally limited to some extent by their toxicity. Use of our product candidates as monotherapies in clinical trials also has resulted in adverse events consistent in nature with other marketed therapies. When

used in combination with other marketed or investigational therapies, our product candidates may exacerbate adverse events associated with the other therapy. If our product candidates, either alone or in combination with other therapies, result in undesirable side effects or have characteristics that are unexpected, we may need to modify or abandon their development.

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

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

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

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

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

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

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

in doing so, the development of our therapeutic product candidates may be adversely affected, our therapeutic product candidates may not receive marketing approval and we may not realize the full commercial potential of any therapeutics that receive marketing approval. As a result, our business would be harmed, possibly materially.

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

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

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

We have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for any approved product, we must either build a sales and marketing organization or outsource these functions to third parties. Subject to approval by the applicable regulatory authorities, we intend to market and sell MM-398 in the United States, while we expect that Baxalta and PharmaEngine will market and sell MM-398 in the rest of the world. Our commercialization plans for our other therapeutic candidates will depend in part on any future collaborations into which we may enter.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, we plan to commercialize MM-398 with a small field force of clinically trained healthcare professionals who will serve as a single point of contact for physicians and other supporting health care professionals involved in the care of patients. This differs from the traditional field model in that it combines the roles of field sales and medical professionals that are sometimes separate roles. While we believe that our field strategy will better meet the needs of our customers, this strategy may not be effective. Additionally, recruiting and training a field 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 field 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 field and marketing personnel.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have based our research and development efforts on our proprietary systems biology-based approach to biomedical research, which we refer to as Network Biology. 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 research and develop regenerative medicines to repair the heart using Network Biology. Silver Creek has received separate funding from investors other than us. Although Silver Creek is currently majority owned by us, in the future we may not be the majority owner of or control Silver Creek or other companies that we establish. If in the future we do not control Silver Creek or any future similar company that we establish, Silver Creek or such other companies could take actions that we do not endorse or with which we disagree, such as using Network Biology in a way that reflects adversely on us. In addition, these companies may have difficulty raising additional funds and could encounter any of the risks in developing and commercializing product candidates to which we are subject.

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

In September 2014, we entered into a license and collaboration agreement with Baxalta for the development and commercialization of MM-398. Prior to this collaboration, we did not have a history of working together with Baxalta. The collaboration involves a complex allocation of rights, provides for milestone payments to us based on the achievement of specified development, regulatory and commercial sale milestones, and provides us with royalty-based revenue if MM-398 is successfully commercialized. We cannot predict the success of the collaboration.

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

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

Baxalta has the right to terminate our agreement for the development and commercialization of MM-398, in whole or with respect to specified territories, at any time and for any reason, upon 180 days' prior written notice. Baxalta 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 Baxalta terminates our agreement at any time, whether on the basis of our uncured material breach or for any other reason, it would delay or prevent our further development of MM-398 and materially harm our business and could accelerate our need for additional capital. In particular, we would have to fund the future clinical development and commercialization of MM-398 outside of the United States on our own, seek another collaborator or licensee for such clinical development and commercialization, or abandon the development and commercialization of MM-398.

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

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

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

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

Collaborations involving our product candidates, including our collaboration with Baxalta, pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- disputes may arise between us and the collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated, such as the termination of our license and collaboration agreement with Sanofi effective December 17, 2014, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

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

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

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

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

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

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

Risks Related to the Manufacturing of Our Product Candidates

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

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

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

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

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

Any other interruption of production at our manufacturing facility also could damage our business. For example, in 2009, we experienced a viral contamination at this facility that required that we shut the facility entirely for decontamination. Because of this contamination, the FDA placed a partial clinical hold on our investigational new drug application for MM-121 until we submitted supporting documentation to the FDA regarding our decontamination procedures. Although we were able to resolve this issue, with the FDA lifting the partial clinical hold in April 2010, other companies have experienced similar contamination problems, and we could experience a similar problem in the future that is more difficult to resolve and could lead to a clinical hold.

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

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

In connection with the termination of our license and collaboration agreement with Sanofi for the development and commercialization of MM-121, we assumed an agreement with a third-party manufacturer for the manufacture of MM-121. We do not have any other agreements with third-party manufacturers for the clinical or commercial supply of any of our product candidates, and we may be unable to conclude such agreements or to do so on acceptable terms. Reliance on third-party manufacturers entails additional risks, including:

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

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

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

We currently rely on single suppliers for the resins, media and filters that we use for our manufacturing process. We purchase these materials from our suppliers on a purchase order basis and do not have long-term supply agreements in place. Any performance failure or refusal to supply on the part of our existing or future suppliers could delay clinical development, marketing approval or commercialization of our products. If our current suppliers cannot perform as agreed, we may be required to replace one or more of these suppliers. Although we believe that there may be a number of potential long-term replacements to each supplier, we may incur added costs and delays in identifying and qualifying any such replacements.

We likely will rely upon third-party manufacturers to provide us with necessary reagents and instruments to develop, test and manufacture our *in vitro* companion diagnostics. Currently, many reagents are marketed as Research Use Only products under FDA regulations.

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 ability to supply our product candidates.

Although we perform much of the bulk manufacturing for our product candidates, we rely on third parties to perform the fill-finish and packaging steps. If any of those third parties were to fail to be in compliance with regulations of the FDA or other regulatory bodies, our ability to supply our product candidates could be adversely impacted.

For instance, in 2010, 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. As a result, we pulled some MM-121 from clinical trial sites and replaced it 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. In addition, the FDA placed a partial clinical hold on our clinical trials of MM-111 until MM-111 filled and packaged by a new third-party contractor that we engaged was available. This restocking resulted in a short delay in the dosing of a few patients without any patients missing a dose. 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-121, MM-141, MM-111 and MM-151, and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The occurrence of such events could materially harm our business.

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

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

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to 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.

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.

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

The process of obtaining regulatory approvals is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based on a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, changes in regulatory review for each submitted product application or approval of other products for the same indication may cause delays in the approval or rejection of an application. Regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and

clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

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

In July 2014, the FDA issued final 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. Even with the issuance of the final 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 clinical stage product candidates, MM-121, MM-141, MM-111 and MM-151, 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 will depend on whether the FDA views the diagnostics to be essential to the safety and efficacy of these therapeutics.

For our two other clinical stage 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 clinical stage product candidates, we would expect that FDA approval of an *in vitro* companion diagnostic, and possibly an *in vivo* companion diagnostic, would be required for approval and subsequent commercialization of each such therapeutic product candidate. We are not aware of any currently available diagnostics that, if necessary, would otherwise allow us to proceed with the approval and subsequent commercialization of our product candidates despite a delay in or failure of our attempts to develop companion diagnostics.

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

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

We have obtained orphan drug designation in the United States and orphan medicinal product designation in the European Union for MM-398 for the treatment of pancreatic cancer. In addition, we have obtained orphan drug designation in the United States for MM-141 for the treatment of pancreatic cancer and for MM-111 for the treatment of esophageal, gastric and gastroesophageal junction cancers. 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 EMA grants orphan medicinal product designation to promote the development of products that may offer therapeutic benefits for life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the European Union. Orphan medicinal product designation from the EMA provides ten years of marketing exclusivity following drug approval, subject to reduction to six years if the designation criteria are no longer met.

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

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

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

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

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

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

A fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process.

In the United States, our most advanced product candidate, MM-398, received fast track designation and priority review status. If a drug is intended for the treatment of a serious or life-threatening disease or condition and the drug demonstrates the potential to address unmet medical needs for this disease or condition, the drug sponsor may apply for FDA fast track designation. If a drug offers major advances in treatment, the drug sponsor may apply for FDA priority review status. The FDA has broad discretion whether or not to grant fast track designation or priority review status, so even if we believe a particular product candidate is eligible for such designation or status, the FDA could decide not to grant it. Even though MM-398 has received fast track designation for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy and priority review status for the NDA for MM-398 in combination with 5-FU and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

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

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

In order to market and sell our products in the European Union and many other jurisdictions, we or our commercialization partners must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve

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

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

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

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

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

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

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.

For example, 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 healthcare 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 revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the 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 healthcare practitioners. We will not know the full effects of the Health Care Reform Law until all applicable federal and state agencies have issued regulations or guidance under the law. Although it is too early to determine the effect of the Health Care Reform Law, the 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.

If we fail to comply with our reporting and payment obligations under U.S. governmental pricing programs, we could be required to reimburse government programs for underpayments and could pay penalties, sanctions and fines which could have a material adverse effect on our business, financial condition and results of operations.

As a condition of reimbursement by various U.S. federal and state healthcare programs, if any of our product candidates are approved by the FDA, we will be required to calculate and report certain pricing information to U.S. federal and state healthcare agencies. For example, we would be required to provide average selling price information to the Centers for Medicare & Medicaid Services on a quarterly basis in order to compute Medicare Part B payment rates. Price reporting and payment obligations are highly complex and vary among products and programs. The calculation of average selling price includes a number of inputs from contracts with wholesalers, specialty distributors, group purchasing organizations and other customers. It would also require us to make an assessment of whether these agreements are deemed to be for bona fide services and that the services are deemed to be at fair market value in our industry and for our products. Our processes for estimating amounts due under these governmental pricing programs will almost certainly involve subjective decisions. As a result, our price reporting calculations would be subject to the risk of errors and our methodologies for calculating these prices could be challenged under the federal False Claims Act or other laws. In addition, the Health Care Reform Law modified the rules related to certain price reports and expanded the scope of pharmaceutical product sales to which Medicaid rebates apply, among other things. Uncertainty exists currently, as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. This uncertainty in the interpretation of the legislation increases the chances of an error in price reporting, which could in turn lead to a legal challenge, restatement or investigation. If we become subject to investigations, restatements or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Commercialization of Our Product Candidates

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted off-label uses, we may become subject to significant fines and other liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant government fines and other related liability. For example, the U.S. government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that can impose significant restrictions and other burdens on the affected companies.

In addition, incentives under applicable U.S. laws encourage employees and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so called whistleblower lawsuits as part of which such persons seek to collect a portion of moneys allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products beyond labeled claims. Such lawsuits, whether with or without merit, are typically time consuming and costly to defend. Such suits may also result in related stockholder lawsuits, which are also costly to defend.

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;
- the U.S. Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from paying, offering to pay, promising or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity, and encompasses many healthcare professionals in many countries under the definition of a foreign government official;
- the Bribery Act, which applies to U.S. companies such as ourselves that conduct business in the United Kingdom, proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official and failing to have adequate procedures to prevent employees and other agents from giving bribes; 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 healthcare 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.

Our corporate compliance efforts cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sales, coverage and reimbursement of our products, together with our general operations, are or will be, if we receive marketing approval for any of our product candidates, subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. While we are implementing a corporate compliance program based on what we believe are the current best practices, we cannot provide any assurance that governmental authorities will find that our business practices comply with current or future administrative or judicial interpretations of potentially applicable laws and regulations. If we fail to comply with any of these laws and regulations, we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, disqualification or debarment from participation in federally-funded healthcare programs or other sanctions or litigation, any of which events may have a significant adverse impact on our business.

Risks Related to Employee Matters and Managing Growth

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially own a large portion of our capital stock. As a result, if these

stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, will significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could allow, delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions:

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

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

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

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

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

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

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

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

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

A substantial portion of our outstanding common stock can be traded without restriction at any time. In addition, a portion of our outstanding common stock is currently restricted as a result of federal securities laws, but can be sold at any time subject to applicable volume limitations. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, by us or others, could reduce the market price of our common stock. In addition, we have a significant number of shares that are subject to outstanding options and warrants, and we may issue shares of our common stock upon conversion of our outstanding convertible senior notes. The exercise of these options and warrants or the issuance of shares of our common stock upon conversion of our outstanding convertible senior notes and the subsequent sale of the underlying common stock could cause a further

decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We cannot predict the size of future issuances or the effect, if any, that any future issuances may have on the market price for our common stock.

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: August 10, 2015

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

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
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.

Exhibit 31.1

CERTIFICATIONS

I, Robert J. Mulroy, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 10, 2015

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

Exhibit 31.2

CERTIFICATIONS

I, William A. Sullivan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 10, 2015

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Merrimack Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Robert J. Mulroy, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2015

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

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Merrimack Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, William A. Sullivan, Chief Financial Officer and Treasurer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 10, 2015

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