

MERRIMACK PHARMACEUTICALS INC

Form S-3ASR

July 13, 2015

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As filed with the Securities and Exchange Commission on July 13, 2015

Registration No. 333-

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

FORM S-3  
REGISTRATION STATEMENT  
*UNDER*  
*THE SECURITIES ACT OF 1933*

MERRIMACK PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

04-3210530  
(I.R.S. Employer  
Identification Number)

**One Kendall Square, Suite B7201**

**Cambridge, Massachusetts 02139**

**(617) 441-1000**

**(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)**

**Robert J. Mulroy**

**President and Chief Executive Officer**

**Merrimack Pharmaceuticals, Inc.**

**One Kendall Square, Suite B7201**

**Cambridge, Massachusetts 02139**

**(617) 441-1000**

**(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)**

*Copies to:*

**Brian A. Johnson, Esq.**

**Wilmer Cutler Pickering Hale and  
Dorr LLP**

**60 State Street**

**Boston, Massachusetts 02109**

**(617) 526-6000**

**Jeffrey A. Munsie, Esq.**

**Vice President and General  
Counsel**

**Merrimack Pharmaceuticals, Inc.**

**One Kendall Square, Suite B7201**

**Cambridge, Massachusetts 02139**

**(617) 441-1000**

**Richard D. Truesdell, Jr., Esq.**

**Davis Polk & Wardwell LLP**

**450 Lexington Avenue**

**New York, New York 10017**

**(212) 450-4000**

**Approximate date of commencement of proposed sale to the public:** From time to time after this registration statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee (2)
Common Stock, par value \$.001 per share	\$40,000,000	\$4,648

- (1) Estimated for purposes of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the Securities Act ).
- (2) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price.

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**Prospectus**

**\$40,000,000**

**Common Stock**

We have entered into a Sales Agreement, or sales agreement, with Cowen and Company, LLC, or Cowen, dated July 13, 2015, relating to the sale of shares of our common stock offered by this prospectus. In accordance with the terms of the sales agreement, under this prospectus we may offer and sell shares of our common stock, \$0.01 par value per share, having an aggregate offering price of up to \$40,000,000 from time to time through Cowen, acting as our agent.

Sales of our common stock, if any, under this prospectus will be made by any method permitted that is deemed an at the market offering as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through The NASDAQ Global Market, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices, and/or any other method permitted by law. Cowen is not required to sell any specific amount, but will act as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cowen will be entitled to compensation at a commission rate of up to 3% of the gross sales price per share sold under the sales agreement. See Plan of Distribution beginning on page 43 for additional information regarding the compensation to be paid to Cowen. In connection with the sale of the common stock on our behalf, Cowen may be deemed to be an underwriter within the meaning of the Securities Act and the compensation of Cowen may be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Cowen with respect to certain liabilities, including liabilities under the Securities Act.

Our common stock trades on The NASDAQ Global Market under the trading symbol MACK . On July 10, 2015, the last sale price of our common stock as reported on The NASDAQ Global Market was \$12.08 per share.

**Investing in our common stock involves risks. See Risk Factors beginning on page 6 of this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**Cowen and Company**

July 13, 2015

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**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a shelf registration process. Under this shelf registration process, we may from time to time sell shares of our common stock having an aggregate offering price of up to \$40,000,000 under this prospectus at prices and on terms to be determined by market conditions at the time of the offering.

Before buying any of the common stock that we are offering, we urge you to carefully read this prospectus and all of the information incorporated by reference herein, as well as the additional information described under the headings **Where You Can Find More Information** and **Incorporation by Reference**. These documents contain important information that you should consider when making your investment decision.

To the extent there is a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporated by reference in this prospectus, on the other hand, you should rely on the information in this prospectus, provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in this prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in or incorporated by reference in this prospectus and any related free writing prospectus filed by us with the SEC. We have not, and Cowen has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any securities other than the securities described in this prospectus or an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information appearing in this prospectus, the documents incorporated by reference and any related free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

You should also read and consider the information in the documents to which we have referred you in the sections entitled **Where You Can Find More Information** and **Incorporation by Reference** in this prospectus.

Unless the context otherwise indicates, references in this prospectus to **Merrimack**, **we**, **our**, **us** and **the Company** collectively, to Merrimack Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus and the information incorporated by reference herein include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained or incorporated by reference in this prospectus, including statements regarding our strategy, future operations, and 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, and other 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 prospectus and the information incorporated by reference herein 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;

our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;  
and

the use of proceeds from this offering.

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. See the

Risk Factors section of this prospectus for more information. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. 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.

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**PROSPECTUS SUMMARY**

*This summary highlights selected information contained elsewhere in this prospectus and in the documents we incorporate by reference. This summary does not contain all of the information you should consider before making an investment decision. You should read this entire prospectus carefully, especially the risks of investing in our common stock discussed under Risk Factors beginning on page 6 of this prospectus, along with our consolidated financial statements and notes to those consolidated financial statements and the other information incorporated by reference in this prospectus.*

**Merrimack Pharmaceuticals, Inc.**

**Our Business**

**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. On June 23, 2015, the U.S. Food and Drug Administration, or FDA, 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. In addition, on May 28, 2015, 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. We also have multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines. We have tailored each of our clinical stage product candidates to target specific disease mechanisms that our research suggests are common across many solid tumor types. We believe that these product candidates have the potential to address major unmet medical needs.

We are also developing *in vitro* and *in vivo* companion diagnostics for use with each of our oncology therapeutic product candidates. Our *in vitro* companion diagnostic agents employ biophysical or biochemical markers of cancer, or biomarkers, which we have identified using our systems biology approach. Our *in vivo* companion diagnostics take the form of imaging agents that may help identify patients likely to benefit from our therapeutic products by measuring deposition of our products in the tumor. We believe that companion diagnostics will allow us to improve the efficiency and productivity of our clinical development and enhance the potential efficacy and pharmacoeconomic benefit of our therapeutics.

We have also entered into an agreement to utilize our 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.

### **Our Clinical Stage Product Candidates**

The table and descriptions below summarize key information about our clinical stage therapeutic product candidates, MM-398, MM-302, MM-121, MM-141, MM-111 and MM-151. All of these product candidates are designed for intravenous administration. None of our product candidates are approved for any indication by the FDA or any other regulatory agency.

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Each of the product candidates described below is a targeted therapy, designed to efficiently act on selected cancer cells. These targeted therapies are either nanotherapeutics that are designed to preferentially deliver cytotoxic therapies to the tumor tissue, such as MM-398 and MM-302, or monoclonal antibodies or monoclonal antibody-derived molecules that are designed to block oncogenic signaling pathways, such as MM-121, MM-141, MM-111 and MM-151.

<b>Program</b>	<b>Clinical Status</b>	<b>Commercial Rights (Territory)</b>
<b>MM-398</b>  (nanotherapeutic encapsulation of irinotecan)	NDA accepted for review by the FDA 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.	Merrimack  (United States)
	MAA accepted for review by the EMA 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.	PharmaEngine (Taiwan)
	Announced top-line results of a Phase 3 clinical trial in combination with 5-FU and leucovorin in patients with metastatic pancreatic cancer whose cancer had progressed on treatment with gemcitabine (NAPOLI-1 trial).	Baxalta  (rest of world outside of United States and Taiwan)
	Conducting investigator-sponsored Phase 1 clinical trials as a monotherapy (utilizing a high concentration formulation of MM-398) in patients with glioma and in combination with cyclophosphamide in patients with pediatric solid tumors.	
	Conducting a Phase 1 translational clinical trial designed to identify predictive imaging biomarkers associated with MM-398 in patients with solid tumors.	
<b>MM-302</b>  (ErbB2 (HER2) targeted antibody drug conjugated liposomal doxorubicin)	Conducting a Phase 2 clinical trial in combination with trastuzumab in patients with ErbB2 (HER2) positive, locally advanced or metastatic breast cancer.	Merrimack  (worldwide)

**MM-121** Conducting a Phase 2 clinical trial in combination with docetaxel or pemetrexed in patients with heregulin positive, locally advanced or metastatic non-small cell lung cancer. Merrimack (worldwide)  
(ErbB3 targeted monoclonal antibody)

Announced top-line results from four Phase 2 clinical trials in combination with chemotherapies and other targeted agents in patients with ovarian, breast and non-small cell lung cancers.

**MM-141** Conducting a Phase 2 clinical trial in combination with nab-paclitaxel and gemcitabine in patients with IGF-1 positive, metastatic pancreatic cancer.\* Merrimack (worldwide)  
(IGF-1R and ErbB3 targeted tetravalent bispecific antibody)

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<b>MM-111</b> (ErbB3 and ErbB2 (HER2) targeted bispecific antibody)	Concluding a Phase 2 clinical trial in combination with paclitaxel and trastuzumab in patients with advanced gastric, esophageal and gastroesophageal junction 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.	Merrimack (worldwide)
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We do not plan to invest in additional development of MM-111 at this time.

<b>MM-151</b> (EGFR (ErbB1) targeted triclonal antibody)	Conducting a Phase 1 clinical trial as a monotherapy and in combination with irinotecan in patients with solid tumors.	Merrimack (worldwide)
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- \* Randomized (1:1), double-blinded, placebo-controlled trial expected to enroll 146 front-line metastatic pancreatic cancer patients who have high serum levels of free IGF-1. The primary endpoint of the trial is progression free survival. Secondary endpoints include overall survival, objective response rate, safety and tolerability.

**Recent Developments**

On June 23, 2015, the FDA accepted for review the NDA for MM-398 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. Priority review status accelerates the FDA's review process for the NDA from a goal of 10 months from the FDA's receipt of the NDA to a goal of six months from the FDA's receipt of 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.

The NDA for MM-398 is based upon the results of our Phase 3 clinical trial of MM-398 in patients with metastatic pancreatic cancer whose cancer had progressed on treatment with gemcitabine, which we refer to as the NAPOLI-1 study. The NAPOLI-1 study was a randomized, open label Phase 3 clinical trial designed to evaluate two MM-398 regimens, 80 mg/m<sup>2</sup> combined with 5-FU and leucovorin every two weeks, and 120 mg/m<sup>2</sup> as a monotherapy every three weeks. Each of these two arms of the trial was compared to a control arm of 5-FU and leucovorin. A total of 417 patients at over 100 sites in North America, South America, Europe, Asia and Australia were randomized across the three arms. The primary endpoint of this trial was a statistically significant difference in overall survival between MM-398, alone or in combination with 5-FU and leucovorin, against the common control arm of the combination of 5-FU and leucovorin. Overall survival is a measure of the time to death from treatment randomization. The combination of MM-398 with 5-FU and leucovorin achieved the primary endpoint for this trial, with a statistically significant survival advantage compared to the control arm.

The most common non-hematologic Grade 3 and higher adverse events in the MM-398 combination arm were fatigue (14%), diarrhea (13%) and vomiting (11%). Hematologic Grade 3 and higher adverse events included neutropenia (20%) and febrile neutropenia (2%).

Data for the NAPOLI-1 study were presented at the European Society for Medical Oncology World Congress on Gastrointestinal Cancer (ESMO GI) in June 2014 and the American Society of Clinical Oncology 2015

Gastrointestinal Cancers Symposium (ASCO GI) in January 2015.

In addition, on May 28, 2015, the EMA accepted for review the MAA filed by Baxalta for MM-398 for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy. In connection with Baxter International Inc.'s planned separation of the Baxalta business, the license and collaboration agreement that we previously entered into with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA for the development and commercialization of MM-398 outside of the United States and Taiwan was assigned to Baxalta during the second quarter of 2015.

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**Company Information**

We were incorporated under the laws of the Commonwealth of Massachusetts in 1993 under the name Immtek, Inc. We changed our name to Atlantic BioPharmaceuticals, Inc. in 1995. In 2001, we acquired Merrimack Pharmaceuticals, Inc., a Delaware corporation, and changed our name to Merrimack Pharmaceuticals, Inc. In October 2010, we reincorporated in the State of Delaware. As a result, we are now a Delaware corporation with the name Merrimack Pharmaceuticals, Inc. Our principal executive offices are located at One Kendall Square, Suite B7201, Cambridge, Massachusetts 02139, and our telephone number is (617) 441-1000. Our website address is [www.merrimackpharma.com](http://www.merrimackpharma.com). The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.



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**THE OFFERING**

<b>Common Stock Offered by Us</b>	Shares of our common stock having an aggregate offering price of up to \$40,000,000.
<b>Manner of Offering</b>	At the market offering that may be made from time to time through our sales agent, Cowen and Company, LLC. See Plan of Distribution.
<b>Use of Proceeds</b>	We intend to use the net proceeds from this offering, together with our other cash resources, to fund our preparation for and potential initiation of the commercial launch in the United States as early as the fourth quarter of 2015 of 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 advancement and clinical development of our other clinical stage product candidates, including MM-398 in additional indications; and our other preclinical and research and development efforts. See Use of Proceeds.
<b>Risk Factors</b>	You should read the Risk Factors section of this prospectus for a discussion of factors to consider carefully before deciding to purchase shares of our common stock.
<b>NASDAQ Global Market Symbol</b>	MACK

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**RISK FACTORS**

*Investing in our common stock involves significant risks. In deciding whether to invest, and in consultation with your own financial and legal advisors, you should carefully consider the following risk factors, as well as the other information contained in this prospectus and in our filings with the Securities and Exchange Commission, or the SEC, that we have incorporated by reference in this prospectus. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects and cause the value of our stock to decline, which could cause you to lose all or part of your investment. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations.*

**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 \$34.4 million for the three months ended March 31, 2015, \$83.6 million for the year ended December 31, 2014 and \$130.7 million for the year ended December 31, 2013. As of March 31, 2015, we had an accumulated deficit of \$689.5 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.

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***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 March 31, 2015, we had outstanding borrowings in an aggregate principal amount of \$40.0 million under a loan and security agreement, as amended, which we refer to as the Loan and Security Agreement, with Hercules Technology Growth Capital, Inc., or Hercules. In addition, in July 2013, we issued \$125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020, which we refer to as the convertible senior notes. 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.

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

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

We expect that the net proceeds from this offering, if we issue and sell shares of our common stock with maximum aggregate sales proceeds of \$40.0 million as specified in this prospectus, together with our unrestricted cash and cash equivalents and available-for-sale securities of \$91.8 million as of March 31, 2015 and \$66.5 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, will enable us to fund our operations, including continued investment in our research and development pipeline, into the second quarter of 2016. See [Use of Proceeds](#) for more information. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount is not determinable at this time. Any revenues from sales of MM-398, if it receives marketing approval, and any additional net milestones related to MM-398 that we receive from Baxalta, after offsetting milestone payments to PharmaEngine, would provide further funding for our operations. 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.

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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 Watson Laboratories, Inc., or 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.





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**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;

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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;

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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.

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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;

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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.

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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.

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***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.

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***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 Pharmaceuticals, Inc., or 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.

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### **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.

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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 and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

For example, in September 2009, we entered into a license and collaboration agreement with Sanofi for the development and commercialization of MM-121. In June 2014, we and Sanofi agreed to terminate the license and collaboration agreement effective December 17, 2014.

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.

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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

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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 expect to assume responsibility for the manufacture of MM-121 by assuming an agreement with a third-party manufacturer. 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.

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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

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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

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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

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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 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.

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***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

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***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.

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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 lead 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.



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***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

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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

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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;

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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.

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**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.

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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 and This Offering**

*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.

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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

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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 this offering or any future issuances may have on the market price for our common stock.

***Our management may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a significant return, if any.***

Our management will have broad discretion over the use of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of this offering. You may not agree with the manner in which our management chooses to allocate and spend these net proceeds. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce significant income or investments that lose value.

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**USE OF PROCEEDS**

We may issue and sell shares of our common stock having aggregate sales proceeds of up to \$40.0 million from time to time. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time.

We intend to use the net proceeds from this offering, together with our other cash resources, to fund our preparation for and potential initiation of the commercial launch in the United States as early as the fourth quarter of 2015 of 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 advancement and clinical development of our other clinical stage product candidates, including MM-398 in additional indications; and our other preclinical and research and development efforts. The balance, if any, will be used to fund capital expenditures, working capital and other general corporate purposes.

We have not determined the exact amounts we plan to spend on any of the items listed above or the timing of these expenditures. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development and commercialization efforts, the status of and results from clinical trials, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We have no current understandings, agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies.

We expect that the net proceeds from this offering, if we issue and sell shares of our common stock with maximum aggregate sales proceeds of \$40.0 million as specified in this prospectus, together with our unrestricted cash and cash equivalents and available-for-sale securities of \$91.8 million as of March 31, 2015 and \$66.5 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, will enable us to fund our operations, including continued investment in our research and development pipeline, into the second quarter of 2016. Based on our planned use of these funds, we expect that such funds will be sufficient to enable us to fund a commercial launch of MM-398 in the United States if it receives marketing approval. We do not expect that such funds will be sufficient to allow us to complete the development of any of our other product candidates. Any revenues from sales of MM-398, if it receives marketing approval, and any additional net milestones related to MM-398 that we receive from Baxalta, after offsetting milestone payments to PharmaEngine, would provide further funding for our operations.

However, it is possible that we will not achieve the progress that we expect because the actual costs and timing of the commercialization of MM-398, as well as the preclinical and clinical development of our other product candidates, are difficult to predict, subject to substantial risks and delays and often vary depending on the particular indication and development strategy.

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**DIVIDEND POLICY**

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. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

Under the Loan and Security Agreement with Hercules, we are prohibited from declaring or paying any cash dividends, or making any cash distributions on, any class of our stock or other equity interest without Hercules' prior written consent.



Table of Contents**DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the price you pay in this offering and the net tangible book value per share of our common stock after this offering.

Our net tangible book value as of March 31, 2015 was \$(140.1) million, or \$(1.28) per share of our common stock, based on approximately 109,386,000 shares of our common stock then outstanding. After giving effect to the assumed sale by us of shares of our common stock in the aggregate amount of \$40.0 million at an assumed public offering price of \$12.08 per share (the last sale price of our common stock on July 10, 2015 as reported on The NASDAQ Global Market), less the estimated commissions and estimated offering expenses payable by us, our net tangible book value at March 31, 2015 would have been \$101.6 million, or \$(0.90) per share. This represents an immediate increase in net tangible book value of \$0.38 per share to existing stockholders and an immediate dilution of \$12.98 per share to investors in this offering. The following table illustrates this per share dilution. The as adjusted information is illustrative only and will adjust based on the actual price to the public, the actual number of shares sold and other terms of the offering determined at the time shares of our common stock are sold pursuant to this prospectus. The shares sold in this offering, if any, will be sold from time to time at various prices.

Assumed public offering price per share		\$ 12.08
Net tangible book value per share as of March 31, 2015	\$ (1.28)	
Increase per share attributable to new investors purchasing shares in this offering	\$ 0.38	
As adjusted net tangible book value per share after giving effect to this offering		(0.90)
Dilution per share to new investors		\$ 12.98

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**DESCRIPTION OF CAPITAL STOCK**

The following description of our capital stock is intended as a summary only. This description is based upon, and is qualified by reference to, our certificate of incorporation, our bylaws and applicable provisions of Delaware corporate law. This summary is not complete. You should read our certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus forms a part, for the provisions that are important to you.

Our authorized capital stock consists of 200,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of June 30, 2015, 110,800,671 shares of common stock were outstanding, and no shares of preferred stock were outstanding.

**Common Stock**

*Voting Rights.* Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. In general, except (1) for the election of directors, (2) as described below under Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law That May Have Anti-Takeover Effects Super-Majority Voting, (3) in the future to the extent that we have two or more classes or series of stock outstanding with separate voting rights and (4) as otherwise required by law, any matter to be voted on by our stockholders at any meeting is decided by the vote of the holders of a majority in voting power of the votes cast by the holders of shares of our stock present or represented at the meeting and voting affirmatively or negatively on such matter.

*Dividends.* Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

*Liquidation and Dissolution.* In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock.

*Other Rights.* Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

*Transfer Agent and Registrar.* Computershare Trust Company, N.A. is the transfer agent and registrar for our common stock.

*NASDAQ Global Market.* Our common stock is listed on The NASDAQ Global Market under the symbol MACK.

**Preferred Stock**

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with

possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Currently, we have no shares of preferred stock outstanding.

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### **Effects of Authorized but Unissued Stock**

We have shares of common stock and preferred stock available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of The NASDAQ Global Market. We may utilize these additional shares for a variety of corporate purposes, including for future public offerings to raise additional capital or facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a controlling interest in our company by means of a merger, tender offer, proxy contest or otherwise. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation.

### **Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law That May Have Anti-Takeover Effects**

*Delaware Law.* We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a business combination with any interested stockholder for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our board of directors, the business combination is approved by our board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A business combination includes, among other things, a merger or consolidation involving us and the interested stockholder and the sale of more than 10% of our assets. In general, an interested stockholder is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

*Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations.* Our certificate of incorporation and our bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our chairman of the board, our president or chief executive officer or our board of directors. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock, because even if it acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

*Super-Majority Voting.* The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage.

Our bylaws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

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**Directors Liability**

Our certificate of incorporation limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty or other duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

for any breach of the director's duty of loyalty to us or our stockholders;

for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

for voting or assenting to unlawful payments of dividends, stock repurchases or other distributions; or

for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the Delaware General Corporation Law is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the Delaware General Corporation Law.

Our certificate of incorporation provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into indemnification agreements with our directors and executive officers. These indemnification agreements may require us, among other things, to indemnify each such director or executive officer, as applicable, for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him in any action or proceeding arising out of his service as one of our directors or executive officers, as applicable.

Certain of our non-employee directors may, through their relationships with their employers, be insured or indemnified against certain liabilities incurred in their capacity as members of our board of directors.

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**PLAN OF DISTRIBUTION**

We have entered into a sales agreement with Cowen and Company, LLC, or Cowen, under which we may issue and sell from time to time up to \$40,000,000 of our common stock through Cowen as our sales agent. Sales of the common stock, if any, will be made at market prices by any method that is deemed to be an at the market offering as defined in Rule 415 under the Securities Act, including without limitation sales made through The NASDAQ Global Market, on any other existing trading market for the common stock or to or through a market maker. In addition, with our prior written consent, Cowen may also sell the common stock in negotiated transactions.

Cowen will offer the common stock subject to the terms and conditions of the sales agreement on a daily basis or as otherwise agreed upon by us and Cowen. We will designate the maximum amount of common stock to be sold through Cowen on a daily basis or otherwise determine such maximum amount together with Cowen. Subject to the terms and conditions of the sales agreement, Cowen will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the NASDAQ Global Market to sell on our behalf all of the shares of common stock requested to be sold by us. We may instruct Cowen not to sell common stock if the sales cannot be effected at or above the price designated by us in any such instruction. We or Cowen may suspend the offering of the common stock being made through Cowen under the sales agreement upon proper notice to the other party. We and Cowen each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party's sole discretion at any time.

Aggregate compensation payable to Cowen as sales agent shall be equal to 3% of the gross sales price of the shares sold through it pursuant to the sales agreement.

Remaining sales proceeds, after deducting any expenses payable by us and any transaction fees imposed by any governmental or self-regulatory organization in connection with the sales, will equal our net proceeds for the sale of such common stock.

Cowen will provide written confirmation to us following the close of trading on The NASDAQ Global Market, each day in which common stock is sold through it as sales agent under the sales agreement. Each confirmation will include the number of shares of common stock sold through it as sales agent on that day, the gross sales price per share, the net proceeds to us and the compensation payable by us to Cowen.

We will report at least quarterly the number of shares of common stock sold through Cowen under the sales agreement, the net proceeds to us and the compensation paid by us to Cowen in connection with the sales of common stock.

Settlement for sales of common stock will occur, unless the parties agree otherwise, on the third business day that is also a trading day following the date on which any sales were made in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sales of the common stock on our behalf, Cowen may be deemed to be an underwriter within the meaning of the Securities Act, and the compensation paid to Cowen may be deemed to be underwriting commissions or discounts. We have agreed in the sales agreement to provide indemnification and contribution to Cowen against certain liabilities, including liabilities under the Securities Act. As sales agent, Cowen will not engage in any transactions that stabilize our common stock.

We estimate that the total expenses of the offering payable by us, excluding commissions payable to Cowen under the sales agreement, will be approximately \$375,000.





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**LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP. Cowen and Company, LLC is being represented in connection with this offering by Davis Polk & Wardwell LLP, New York, New York.

**EXPERTS**

The financial statements and management's assessment of the effectiveness of internal control over financial reporting (which is included in Management's Report on Internal Control over Financial Reporting) incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2014 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. Copies of certain information filed by us with the SEC are also available on our website at <http://www.merrimackpharma.com>. Our website is not a part of this prospectus and is not incorporated by reference in this prospectus. You may also read and copy any document we file at the SEC's Public Reference Room, 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the Public Reference Room.

This prospectus is part of a registration statement we filed with the SEC. This prospectus omits some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information and exhibits in the registration statement for further information on us and our consolidated subsidiaries and the securities we are offering. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements.

**INCORPORATION BY REFERENCE**

The SEC allows us to incorporate by reference much of the information we file with the SEC, which means that we can disclose important information to you by referring you to those publicly available documents. The information that we incorporate by reference in this prospectus is considered to be part of this prospectus. Because we are incorporating by reference future filings with the SEC, this prospectus is continually updated and those future filings may modify or supersede some of the information included or incorporated in this prospectus. This means that you must look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or in any document previously incorporated by reference have been modified or superseded. This prospectus incorporates by reference the documents listed below (File No. 001-35409) and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (in each case, other than those documents or the portions of those documents not deemed to be filed) until the offering of the securities under the registration statement is terminated or completed:

Annual Report on Form 10-K for the fiscal year ended December 31, 2014, including the information specifically incorporated by reference into the Annual Report on Form 10-K from our definitive proxy

statement for the 2015 Annual Meeting of Stockholders;

Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2015;

Current Reports on Form 8-K filed on January 22, 2015, February 13, 2015, May 14, 2015 and June 16, 2015; and

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The description of our common stock contained in our Registration Statement on Form 8-A filed on January 27, 2012, including any amendments or reports filed for the purpose of updating such description. You may request a copy of these filings, at no cost, by writing or telephoning us at the following address or phone number:

Merrimack Pharmaceuticals, Inc.

One Kendall Square, Suite B7201

Cambridge, Massachusetts 02139

(617) 441-1000

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**\$40,000,000**

**Common Stock**

**Prospectus**

**Cowen and Company**

July 13, 2015

**Table of Contents****PART II.****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution.\***

Set forth below is an estimate (except in the case of the SEC registration fee) of the amount of fees and expenses to be incurred by the Registrant in connection with the issuance and distribution of the offered securities, other than commissions.

SEC registration fee	\$ 4,648
Printing fees and expenses	5,000
Accounting fees and expenses	50,000
Legal fees and expenses	300,000
Miscellaneous	15,352
 Total	 \$ 375,000

\* All amounts except the SEC registration fee are estimated.

**Item 15. Indemnification of Directors and Officers.**

Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of its directors or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his or her duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. The Registrant's certificate of incorporation provides that no director shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the Delaware General Corporation Law prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnify for such expenses which the Court of Chancery or such other court shall deem proper.

The Registrant's certificate of incorporation provides that it will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding whether civil, criminal, administrative or investigative (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, the Registrant's director or officer, or is or was serving, or has agreed to serve, at the Registrant's request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an Indemnitee), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the Registrant's best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful.

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The Registrant's certificate of incorporation also provides that the Registrant will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of the Registrant to procure a judgment in its favor by reason of the fact that the Indemnitee is or was, or has agreed to become, the Registrant's director or officer, or is or was serving, or has agreed to serve, at the Registrant's request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the Registrant's best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the Registrant, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by the Registrant against all expenses (including attorneys' fees) actually and reasonably incurred by him or her or on his or her behalf in connection therewith. If the Registrant does not assume the defense, expenses must be advanced to an Indemnitee under certain circumstances.

The Registrant has entered into indemnification agreements with its directors and executive officers. In general, these agreements provide that the Registrant will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as a director or officer of the Registrant or in connection with their service at the Registrant's request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director or executive officer makes a claim for indemnification and establish certain presumptions that are favorable to the director or executive officer.

The Registrant maintains a general liability insurance policy which covers certain liabilities of its directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers.

### **Item 16. Exhibits.**

The exhibits to this Registration Statement are listed in the exhibit index, which appears elsewhere herein and is incorporated herein by reference.

### **Item 17. Undertakings.**

The undersigned Registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933, as amended (the Securities Act );
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of this registration statement (or the most recent post-effective amendment thereof) which, individually or in the

aggregate, represent a fundamental change in the information set forth in this registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

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(iii) to include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in this registration statement; *provided, however*, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by a Registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act ), that are incorporated by reference in this registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of this registration statement.

(2) That, for the purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at the time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) each prospectus filed by a Registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of a Registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned Registrant undertakes that in a primary offering of securities of such undersigned Registrant pursuant to this registration statement, regardless of the

underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, such undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) any preliminary prospectus or prospectus of such undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

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- (ii) any free writing prospectus relating to the offering prepared by or on behalf of such undersigned Registrant or used or referred to by such undersigned Registrant;
  - (iii) the portion of any other free writing prospectus relating to the offering containing material information about such undersigned Registrant or its securities provided by or on behalf of such undersigned Registrant; and
  - (iv) any other communication that is an offer in the offering made by such undersigned Registrant to the purchaser.
- (6) That, for purposes of determining any liability under the Securities Act, each filing of the Registrant's annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (7) That, for purposes of determining any liability under the Securities Act:
- (i) the information omitted from the form of prospectus filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective; and
  - (ii) each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of any Registrant pursuant to the indemnification provisions described herein, or otherwise, each Registrant has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by a Registrant of expenses incurred or paid by a director, officer or controlling person of such Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, such Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Table of Contents**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on this 13<sup>th</sup> day of July, 2015.

MERRIMACK PHARMACEUTICALS, INC.

By: /s/ Robert J. Mulroy  
 Robert J. Mulroy  
 President and Chief Executive Officer

**POWER OF ATTORNEY AND SIGNATURES**

We, the undersigned officers and directors of Merrimack Pharmaceuticals, Inc., hereby severally constitute and appoint Robert J. Mulroy and William A. Sullivan, and each of them singly, our true and lawful attorneys with full power to any of them, and to each of them singly, to sign for us and in our names in the capacities indicated below the Registration Statement on Form S-3 filed herewith and any and all amendments (including post-effective amendments) to said Registration Statement, and any registration statement filed pursuant to Rule 462 under the Securities Act of 1933, as amended, in connection with said Registration Statement, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, and generally to do all such things in our name and on our behalf in our capacities as officers and directors to enable Merrimack Pharmaceuticals, Inc. to comply with the provisions of the Securities Act of 1933, as amended, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Robert J. Mulroy Robert J. Mulroy	President, Chief Executive Officer and Director (Principal Executive Officer)	July 13, 2015
/s/ William A. Sullivan William A. Sullivan	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	July 13, 2015
/s/ Gary L. Crocker Gary L. Crocker	Chairman of the Board	July 13, 2015
/s/ John M. Dineen	Director	July 13, 2015

John M. Dineen

/s/ Vivian S. Lee, M.D., Ph.D.

Director

July 13, 2015

Vivian S. Lee, M.D., Ph.D.

/s/ John Mendelsohn, M.D.

Director

July 13, 2015

John Mendelsohn, M.D.

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<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Ulrik B. Nielsen, Ph.D. Ulrik B. Nielsen, Ph.D.	Director	July 13, 2015
/s/ Michael E. Porter, Ph.D. Michael E. Porter, Ph.D.	Director	July 13, 2015
/s/ James H. Quigley James H. Quigley	Director	July 13, 2015
/s/ Russell T. Ray Russell T. Ray	Director	July 13, 2015

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
1.1	Sales Agreement, dated as of July 13, 2015, between the Registrant and Cowen and Company, LLC
3.1	Restated Certificate of Incorporation of the Registrant (filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-180996) and incorporated herein by reference)
3.2	Amended and Restated Bylaws of the Registrant (filed as Exhibit 3.5 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-175427), and incorporated herein by reference)
5.1	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP
23.1	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm for the Registrant
23.2	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1)
24.1	Powers of Attorney (included on the signature pages to the Registration Statement)