MERRIMACK PHARMACEUTICALS INC
Form 10-K
February 27, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2014

or

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

For the transition period from _____ to _____

Commission file number 001-35409

Merrimack Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**04-3210530**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One Kendall Square, Suite B7201	
Cambridge, MA	**02139**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (617) 441-1000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.01 par value	**NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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	x	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

Aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last sale price for such stock on June 30, 2014: $707,644,419.

As of February 13, 2015, there were 106,934,746 shares of Common Stock, $0.01 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2015 Annual Meeting of Stockholders. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

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

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

- our plans to develop and commercialize our most advanced product candidates and companion diagnostics;
- our ongoing and planned discovery programs, preclinical studies and clinical trials;
- the timing of the completion of our clinical trials and the availability of results from such trials;
- our collaborations with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, which we collectively refer to as Baxter, 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 Network Biology approach to drug research and development;
- the potential use of our Network Biology approach in fields other than oncology; and

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

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

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

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PART I

Item 1. 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 currently have six targeted therapeutic oncology candidates in clinical development. Our most advanced program is our investigational agent MM-398. We have initiated a New Drug Application, or NDA, submission with the U.S. Food and Drug Administration, or FDA, for MM-398 as a treatment for metastatic pancreatic cancer in combination with 5-fluorouracil, or 5-FU, and leucovorin in patients who have been previously treated with gemcitabine. Additionally, we have multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines. We have tailored each of our six most advanced 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 Most Advanced Product Candidates

The table and descriptions below summarize key information about our six most advanced therapeutic product candidates, MM-398, MM-302, MM-121, MM-111, MM-151 and MM-141. 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-111, MM-151 and MM-141.

Program	Clinical Status	Commercial Rights (Territory)
MM-398 (nanotherapeutic encapsulation of irinotecan)	Initiated an NDA submission with the FDA as a treatment for metastatic pancreatic cancer in combination with 5-FU and leucovorin in patients who have been previously treated with gemcitabine	Merrimack (United States)
	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)	PharmaEngine (Taiwan)
	Conducting investigator-sponsored Phase 1 clinical trials as a monotherapy in patients with glioma and in combination with cyclophosphamide in patients with pediatric solid tumors	Baxter (rest of world outside of United States and Taiwan)
	Conducting a Phase 1 translational clinical trial designed to identify predictive biomarkers associated with MM-398	
MM-302 (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 (ErbB3 targeted monoclonal antibody)	Conducting a Phase 2 clinical trial in combination with docetaxel or pemetrexed in patients with heregulin positive, advanced non-small cell lung cancer	Merrimack (worldwide)
	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-111 (ErbB3 and ErbB2 (HER2) targeted bispecific antibody)	Conducting 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, or DSMB, for the clinical trial, which cited shorter progression	Merrimack (worldwide)

	free survival, or PFS, on the treatment arm relative to the control arm in the overall patient population. We do not plan to invest in additional development of MM-111 at this time.	
MM-151 (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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Program	Clinical Status	Commercial Rights (Territory)
MM-141 (IGF-1R and ErbB3 targeted tetravalent bispecific antibody)	Conducting a Phase 1 clinical trial as a monotherapy, in combination with everolimus and in combination with nab-paclitaxel and gemcitabine in patients with solid tumors	Merrimack (worldwide)

MM-398

MM-398 overview

Our most advanced product candidate is MM-398 (irinotecan liposome injection), also known as nal-IRI. MM-398 is a nanoliposomal encapsulation of the marketed chemotherapy drug irinotecan. In 2014, we announced results of a Phase 3 clinical trial of MM-398 in patients with metastatic pancreatic cancer whose cancer had progressed on treatment with the chemotherapy drug gemcitabine. Based on the results of that trial, which are described below, we have initiated an NDA submission with the FDA for MM-398 as a treatment for metastatic pancreatic cancer in combination with 5-FU and leucovorin in patients who have been previously treated with gemcitabine. In November 2014, the FDA granted us a fast track designation for this NDA, which allows for a rolling submission of the application. Although our Phase 3 clinical trial of MM-398 focused on pancreatic cancer, we believe that MM-398 may have potential uses in a number of other solid tumor indications, including colorectal cancer, lung cancer, breast cancer, gastric cancer, glioma and pediatric solid tumors.

We hold development and commercialization rights for MM-398 in the United States. In September 2014, we established a collaboration with Baxter for the development and commercialization of MM-398 outside of the United States and Taiwan. PharmaEngine holds the development and commercialization rights to MM-398 in Taiwan.

In July 2011, the FDA granted MM-398 orphan drug designation for the treatment of pancreatic cancer. In September 2011, the European Medicines Agency, or EMA, granted MM-398 orphan medicinal product designation for the treatment of pancreatic cancer.

The encapsulated ingredient of MM-398, irinotecan, is a well-known and widely used chemotherapy. The activated form of irinotecan is SN-38, which functions by inhibiting topoisomerase I, an essential enzyme involved in DNA transcription and replication, and promoting cell death. Dosing with free irinotecan, as with other chemotherapies, is limited by significant adverse effects and rapid clearance that, in turn, limit efficacy. In addition, as with other chemotherapies, the efficacy of irinotecan is limited by tumor resistance mechanisms. MM-398 has demonstrated extended circulation in comparison to free irinotecan in the clinical setting.

MM-398 Phase 3 clinical trial for metastatic pancreatic cancer

In 2014, we announced results from our Phase 3 clinical trial of MM-398 in patients with metastatic pancreatic cancer whose cancer had progressed on treatment with gemcitabine. This clinical trial, which we refer to as the NAPOLI-1 study, was a randomized, open label Phase 3 clinical trial designed to evaluate two MM-398 regimens, 80 mg/m^2 combined with 5-FU and leucovorin every two weeks, and 120 mg/m^2 as a monotherapy every three weeks. Each arm 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 combination of MM-398 with 5-FU and leucovorin achieved an overall survival of 6.1 months, a 1.9 month improvement over the 4.2 month survival demonstrated by the control arm of 5-FU and leucovorin alone. The primary log-rank analysis of overall survival for the MM-398 combination arm was statistically significant (p=0.0009) with a corresponding stratified hazard

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ratio of 0.57. A hazard ratio, or HR, is a measure of how often a particular event happens in one group compared to how often it happens in another group over time. In cancer research, hazard ratios are often used in clinical trials to measure survival at any point in time in a group of patients who have been given a specific treatment compared to a control group given another treatment or a placebo. A hazard ratio of one means that there is no difference in survival between the two groups, while a hazard ratio of greater than one or less than one means that survival was better in one of the groups. A statistically significant advantage in PFS was also observed in the combination arm, with a median of 3.1 months compared to 1.5 months in the control arm. PFS is the time from the initiation of treatment to tumor progression based on an increase of at least 20% in the sum of measured tumor diameters with no new tumors. The combination arm also showed a statistically significant difference in objective response rate compared to the control arm (16% and 1%, respectively, $p<0.001$). Objective response rate is the sum of the complete response rate, which measures the disappearance of all target and non-target tumors, plus the partial response rate, which measures the overall tumor regression based on a decrease of a least 30% of the sum of measured tumor diameters with no new tumors according to Response Evaluation Criteria in Solid Tumors (RECIST v1.1).

The most common non-hematologic Grade 3 and higher adverse events in the MM-398 combination arm were fatigue (14%), diarrhea (13%) and vomiting (11.1%). Hematologic Grade 3 and higher adverse events included neutropenia, which was observed in 20% of patients as determined by objective laboratory values, and febrile neutropenia, which was observed in 2% of patients.

The MM-398 monotherapy arm did not achieve a statistically significant survival advantage compared to the control arm in this trial, with a 4.9 month median overall survival compared to 4.2 months in the control arm. For the monotherapy arm, the stratified hazard ratio for overall survival was 0.93 with a corresponding p-value of 0.5545. In general, patients experienced a higher level of adverse events with the MM-398 monotherapy dose and treatment schedule compared to patients who received the combination of MM-398 with 5-FU and leucovorin.

MM-398 other clinical trials

MM-398 previously met its primary efficacy endpoints in two Phase 2 clinical trials, one in pancreatic cancer patients and one in gastric cancer patients. We are also collaborating with several investigators to conduct additional trials of MM-398, including an investigator-sponsored Phase 2 clinical trial in colorectal cancer, an investigator-sponsored Phase 1 clinical trial in glioma and an investigator-initiated Phase 1 clinical trial in pediatric solid tumors, which is being conducted under our investigational new drug application, or IND.

MM-398 companion diagnostic development

We believe that deposition of nanotherapeutics such as MM-398 in the tumor may be important to efficacy. We are exploring development of *in vivo* companion diagnostics that take the form of imaging agents that may serve as surrogate biomarkers for estimating MM-398 deposition in patient tumors. The companion diagnostic may help identify patients most likely to benefit from nanotherapeutics, and direct those patients with low deposition tumors towards alternate therapy strategies (that may or may not still involve nanotherapeutics). We are currently evaluating various agents imaged by MRI and other modalities to assess the potential for predicting drug deposition. We conducted a Phase 1 translational study at one site in the United States designed to test the feasibility of an MRI-based approach to assess large-particle delivery and tumor macrophage uptake using a marketed iron supplement as an imaging agent and to identify predictive biomarkers associated with MM-398 in various cancers, and recently opened an expansion phase to this translational study that will enroll triple negative breast cancer patients, hormone receptor positive breast cancer patients and breast cancer patients with brain metastases. As part of our preclinical and clinical translational research, we are also investigating functional *in vitro* biomarkers that may be predictive of efficacy in poorly vascularized tumors.

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MM-302

MM-302 overview

MM-302 is an antibody drug conjugated liposomal doxorubicin that targets the ErbB2 (HER2) receptor. Doxorubicin is a marketed chemotherapy that is a member of the anthracycline class of chemotherapies. The addition of anthracyclines to the treatment of both solid and liquid tumors has historically improved outcomes for patients and, specifically, has been an effective component of breast cancer treatment for decades, with free doxorubicin-based regimens providing consistent clinical benefit. However, significant adverse events, including acute and chronic cardiotoxic effects, have limited the use of traditional anthracyclines in combination with targeted therapies, such as trastuzumab, for treatment of ErbB2 (HER2) positive breast cancer. Liposomal doxorubicin (Doxil®), which has been shown to reduce cardiotoxicity associated with free doxorubicin, has been approved for use in certain settings, but has not been approved for use in the United States for the treatment of breast cancer. We designed MM-302 to target and bind to cancer cells that overexpress ErbB2 (HER2) and thereby release doxorubicin at the site of the tumor, while minimizing uptake into normal cells, including those of the heart.

We believe that MM-302 may offer advantages in comparison with other forms of doxorubicin, namely free doxorubicin and liposomal doxorubicin. Our clinical development strategy is to demonstrate that MM-302 has favorable efficacy and safety compared to doxorubicin for the treatment of metastatic breast cancer where concerns over cardiac safety, particularly in combination with trastuzumab, have led to a decline in the use of anthracyclines despite proven efficacy.

MM-302 Phase 2 clinical trial

In August 2014, we initiated a global, open-label, randomized Phase 2 clinical trial of MM-302 in combination with trastuzumab (Herceptin®) in patients with ErbB2 (HER2) positive, locally advanced or metastatic breast cancer. The trial was designed with input from the FDA to support a potential accelerated approval application. The trial has also been reviewed by the EMA, and we intend to use data from the trial, if positive, to support conditional marketing authorization in Europe. This clinical trial, which we refer to as the HERMIONE trial, is expected to enroll approximately 250 patients who will be randomized (1:1) to receive either MM-302 and trastuzumab or chemotherapy of their physician s choice (capecitabine, gemcitabine or vinorelbine) and trastuzumab. Eligible patients for the HERMIONE trial must have received prior treatment with trastuzumab in any setting, and pertuzumab (Perjeta®) and ado-trastuzumab emtansine (T-DM1, Kadcyla®) in the locally advanced or metastatic setting, but have not been treated with an anthracycline-based regimen. The primary endpoint of the trial is PFS. Secondary endpoints include overall survival, objective response rate, safety and tolerability. The trial will be conducted at approximately 60 sites in the United States, Canada and Europe.

Prior to initiating the HERMIONE trial, we conducted a Phase 1 clinical trial of MM-302 in patients with advanced ErbB2 (HER2) positive breast cancer. The purpose of that Phase 1 clinical trial was to assess the safety of MM-302 and identify the maximum tolerated dose. Reported interim results from this trial showed a median PFS of 5.7 months (95% CI [3.1-10.9]) in a heavily pretreated (median of four prior lines of therapy) population of 47 patients receiving a therapeutic dose of MM-302 (30 mg/m2 or greater) alone or in combination with trastuzumab. Patients who had not received prior anthracycline-based chemotherapy treatment had a median PFS of 10.9 months (95% CI [1.7-NC]) and a 35% objective response rate. The most common adverse events in the Phase 1 clinical trial were fatigue, nausea and decreased appetite. Neutropenia was the most common Grade 3/4 adverse event, occurring in seven patients, of which six were in the monotherapy arms and one was in the combination arm. One dose limiting toxicity, febrile neutropenia, was observed in the Phase 1 clinical trial, and the dose was subsequently withheld from the patient. The patient went on to continue study treatment for three additional cycles. Cardiac events, which are a side effect that has

limited the use of anthracyclines, were infrequent in the Phase 1 clinical trial, with three out of 47 patients (6%) experiencing declines in ejection fraction. None of these events were serious adverse events. Consistent with the design of this Phase 1 clinical trial to principally test for safety and dosage tolerance, it was not designed to test for statistical significance of anti-tumor activity.

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MM-302 companion diagnostic development

We believe that deposition of nanotherapeutics such as MM-302 in the tumor may be important to efficacy. We are exploring development of *in vivo* companion diagnostics that take the form of imaging agents that may help identify patients likely to benefit from nanotherapeutics by enabling the measurement of deposition in patient tumors and excluding those patients with low deposition whose tumors are therefore unlikely to respond to treatment with a nanotherapeutic. We are currently evaluating nanotherapeutic formulations of liposomal agents imaged by PET/CT scan and other modalities to assess the potential for measuring deposition.

MM-121

MM-121 overview

MM-121 is a fully human monoclonal antibody that targets ErbB3, a cell surface receptor that is activated by the ligand heregulin. An antibody is a type of protein normally produced by cells of the immune system that binds to just one epitope, or chemical structure, on a protein or other molecule. MM-121 was designed to inhibit cancer growth directly, restore a tumor s sensitivity to drugs to which it has become resistant, and delay the development of resistance by a tumor to other agents.

Research suggests that ErbB3 signaling is primarily activated through binding of its ligand heregulin, and that it is often critical to the growth and survival of tumors. Further data shows that the use of ErbB3 signaling as a resistance mechanism by cancer cells to a variety of cancer therapies often occurs across patient populations and tumor types. Since MM-121 directly inhibits binding of heregulin to ErbB3 and as such prevents activation of this critical pathway, we believe that MM-121 may be effective when given in combination with various standard therapies, offering the following potential advantages compared to existing therapies alone:

- the ability to synergistically or additively inhibit tumor growth, based on our preclinical research involving a broad range of combination therapies;
- the ability to delay the development of resistance to other agents, based on research by us and others demonstrating that ErbB3 signaling is upregulated in response to treatment with other therapies; and
- the ability to restore sensitivity to drugs, based on our preclinical research involving several cell types and xenograft models that are resistant to targeted therapies or chemotherapies.

Based on the central role of heregulin and ErbB3 in cancer growth and survival, we believe that MM-121 may be applicable to a broad range of metastatic tumors, including lung, prostate, breast, ovarian, colon and pancreatic cancers. Our preclinical studies of several hundred tumor samples and the analysis of tumor samples from our Phase 2 clinical trials suggest that MM-121 may be able to target heregulin-dependent ErbB3 signaling that is relevant in approximately 35-50% or more of cancer patients with these types of tumors.

MM-121 Phase 2 clinical trials

We have evaluated MM-121 in multiple Phase 1 and Phase 2 clinical trials in combination with both chemotherapies and other targeted agents across a wide spectrum of solid tumor patient populations, including patients with ovarian,

breast and lung cancers. The goal of our MM-121 clinical program is to explore the efficacy and safety of MM-121 in combination with other targeted ErbB agents such as erlotinib, chemotherapies such as paclitaxel, and anti-hormonal agents such as exemestane, and to evaluate biomarkers that identify patients most likely to benefit from MM-121. We have sought to assess whether efficacy is improved by measuring the ability of various MM-121 combinations to enhance anti-tumor activity or to delay resistance or restore sensitivity to the other therapies.

We announced new or updated results in 2014 from the four Phase 2 clinical trials described below. Our three Phase 2 clinical trials in metastatic cancers, which are the trials in ovarian, breast and lung cancers listed immediately below, enrolled a total of 464 patients and evaluated whether MM-121 in combination with a

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standard of care therapy was more effective than the standard of care therapy alone in prolonging PFS. As ErbB3 signaling was expected to be active in only a subset of patients, pre-treatment biopsies were collected from patients in the lung and ovarian studies and archived tumor tissue in all three studies to assess heregulin, along with four other pre-specified biomarkers. Secondary analyses included evaluation of the pre-specified biomarkers, as well as overall survival and safety data. Across the studies, there was a consistent but modest and tolerable increase in adverse events when MM-121 was combined with erlotinib, paclitaxel and exemestane. Most adverse events were reported as mild to moderate in severity and included diarrhea, fatigue, vomiting, rash, hypokalemia and stomatitis.

Phase 2 clinical trial of MM-121 in combination with paclitaxel for platinum resistant or refractory advanced ovarian cancer

This clinical trial was designed as a global, open-label, randomized Phase 2 clinical trial evaluating whether the combination of MM-121 and paclitaxel was more effective in prolonging PFS than paclitaxel alone in patients (n=220) with locally advanced/metastatic or recurrent epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer, and who had received at least one prior platinum-based chemotherapy regimen and were platinum-resistant or refractory. The study analysis was conducted after 171 events. Of the 220 patients in this clinical trial, biomarker data were available for 151 patients.

	Full Population (N=220)		**Heregulin Positive, ErbB2 (HER2) Low (N=57 of 151)**	
	MM-121 + Paclitaxel	Paclitaxel	MM-121 + Paclitaxel	Paclitaxel
Median PFS	3.7 months	3.7 months	5.7 months	3.5 months
Hazard Ratio	1.05 (95% CI [0.76-1.44])		0.37 (95% CI [0.18-0.76])	
p-value	0.77		0.007	

The HR for PFS is a measurement of the chance of disease progression for the treatment arm relative to the control arm, with an HR of less than one indicating that a patient will likely progress less quickly on the treatment arm than on the control arm, and an HR of more than one indicating the opposite. Because a trial represents a sample of a much larger population, the reported HR from a trial is an estimate of the true HR. The confidence interval, or CI, given after the HR reflects the amount of certainty in the estimate of the HR. An HR value that is not contained within a 95% CI is unlikely to be the true HR. The addition of MM-121 did not significantly enhance paclitaxel activity in an unselected platinum-resistant ovarian cancer population. A subset of heregulin positive patients (38%) who also had low ErbB2 (HER2) levels, however, responded poorly to paclitaxel alone and had improved PFS with the addition of MM-121. There was a consistent but modest and tolerable increase in adverse events when MM-121 was combined with paclitaxel. Further confirmatory studies of MM-121 in ovarian cancer are being considered.

Phase 2 clinical trial of MM-121 in combination with exemestane in metastatic ER/PR+, ErbB2 (HER2) negative breast cancer

This clinical trial was a randomized, double-blinded, placebo-controlled Phase 2 clinical trial evaluating whether the combination of exemestane and MM-121 was more effective in prolonging PFS than exemestane plus placebo in postmenopausal ER/PR+ metastatic breast cancer patients (n=115) who have previously failed anti-estrogen therapy. The primary objective was to compare PFS between the groups. The clinical trial was powered to detect a HR of less than 0.5. The study analysis was conducted after 84 events. Of the 115 patients in this clinical trial, biomarker data were available for 76 patients.

	Full Population (N=115)		**Heregulin Positive (N=34 of 76)**	
	MM-121 + Exemestane	Exemestane	MM-121 + Exemestane	Exemestane
Median PFS	3.7 months	2.5 months	3.8 months	1.9 months
Hazard Ratio	0.77 (95% CI [0.5-1.2])		0.26 (95% CI [0.11-0.63])	
p-value	0.25		0.003	

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The addition of MM-121 did not significantly enhance exemestane activity in an unselected metastatic breast cancer population. There was a consistent but modest and tolerable increase in adverse events when MM-121 was combined with exemestane. Further confirmatory studies of MM-121 in breast cancer are being considered.

Phase 2 clinical trial of MM-121 in combination with erlotinib in EGFR wild-type non-small cell lung cancer

This clinical trial was a global, open-label, randomized parallel cohort Phase 2 clinical trial evaluating whether the combination of MM-121 and erlotinib was more effective in prolonging PFS than erlotinib alone in epidermal growth factor receptor, or EGFR, wild-type (wt) non-small cell lung cancer, or NSCLC, patients (n=129). The reported cohort was previously referred to as Group A, and is the cohort for which sufficient biomarker data was available for biomarker analysis. The primary objective was to compare PFS between the groups. The study analysis was conducted after 105 events. Of the 129 patients enrolled, biomarker data were available for 69 patients.

	Full Population (N=129)		**Heregulin Positive (N=37 of 69)**	
	MM-121 + Erlotinib	Erlotinib	MM-121 + Erlotinib	Erlotinib
Median PFS	1.9 months	1.8 months	1.9 months	1.6 months
Hazard Ratio	0.81 (95%CI [0.55-1.2])		0.35 (95% CI [0.16-0.76])	
p-value	0.29		0.008	

The addition of MM-121 did not significantly enhance erlotinib activity in an unselected NSCLC population. A subset of heregulin positive patients (54%), however, responded poorly to erlotinib alone and had improved PFS with the addition of MM-121. There was a consistent but modest and tolerable increase in adverse events when MM-121 was combined with erlotinib. Further confirmatory studies of MM-121 in NSCLC are being considered, although likely not in combination with erlotinib.

Phase 2 neoadjuvant clinical trial of MM-121 in combination with paclitaxel for ErbB2 (HER2) negative breast cancer

This clinical trial was a randomized, open label Phase 2 neoadjuvant clinical trial of MM-121 in combination with paclitaxel, an established chemotherapy, in patients with ErbB2 (HER2) negative breast cancer. The primary efficacy endpoint of this trial was pathologic complete response, or pCR, rate at time of surgery. pCR measures the absence of invasive cancer in breast and lymph node tissue following neoadjuvant therapy. The trial enrolled 200 patients across the following two populations of ErbB2 (HER2) negative breast cancer patients:

Group A: patients whose tumors are estrogen receptor, or ER, positive and ErbB2 (HER2) negative and have not undergone prior treatment or surgery; and

Group B: patients whose tumors are ER negative, ErbB2 (HER2) negative and progesterone receptor negative, often referred to as triple negative breast cancer, or TNBC, and have not undergone prior treatment or surgery.

Each population of patients was randomized (2:1) to receive either MM-121 in combination with paclitaxel or paclitaxel alone. Following treatment with MM-121 and/or paclitaxel, patients received standard treatment with doxorubicin and cyclophosphamide, two marketed chemotherapies, prior to surgical resection.

In 2014, we announced updated results that included data from both groups. In Group A, patients with an evaluable resection in the treatment arm who received the combination of MM-121 and paclitaxel achieved a pCR rate of 10.6% (95% CI [5.3-20.6]) compared to a pCR rate of 3.3% (95% CI [0.6-16.7]) for those in the control arm. In Group B, patients with an evaluable resection in the treatment arm who received the combination

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of MM-121 and paclitaxel achieved a pCR rate of 42.9% (95% CI [30.8-55.9]) compared to a pCR rate of 51.7% (95% CI [34.4-68.6]) for those in the control arm. There was no formal quantitative endpoint specified for this study.

MM-121 recently initiated Phase 2 clinical trial

In February 2015, we initiated a global, open-label, biomarker-selected, randomized Phase 2 clinical trial of MM-121 in combination with docetaxel or pemetrexed versus docetaxel or pemetrexed alone in patients with heregulin positive, locally advanced or metastatic NSCLC. As part of this trial, we expect to enroll approximately 120 heregulin positive patients that will be randomized (2:1) to receive either MM-121 plus the investigator s choice of docetaxel or pemetrexed, or the investigator s choice of docetaxel or pemetrexed alone. Eligible patients for the trial must have failed prior treatment with no more than two lines of therapy for locally advanced or metastatic disease. The primary endpoint of the trial is PFS. Secondary endpoints include overall survival, objective response rate, safety and tolerability. We plan to conduct the trial at sites in the United States, Canada and Europe.

MM-121 companion diagnostic development

We are developing a companion diagnostic that is focused on measuring certain mechanistically related biomarkers to determine whether a tumor is dependent on ErbB3 signaling and therefore amenable to treatment with MM-121. In 2014, we announced updated biomarker results from a meta-analysis of three randomized clinical trials of MM-121 in patients with ovarian, breast and lung cancers. This analysis included biomarker and efficacy results that had previously been disclosed, as well as additional biomarker data from the Phase 2 metastatic breast cancer trial that had not previously been reported. This meta-analysis highlighted heregulin as the principal biomarker for MM-121 efficacy. High levels of heregulin mRNA correlated with favorable hazard ratios in all three settings: in ovarian cancer, heregulin-high patients had a PFS HR of 0.37 (95% CI [0.18 0.76]) (57 of 151 evaluable patients; prevalence of 38%); in breast cancer, heregulin-high patients had a PFS HR of 0.26 (95% CI [0.11 0.63]) (34 of 76 evaluable patients; prevalence of 45%); in lung cancer, heregulin-high patients had a PFS HR of 0.35 (95% CI [0.16 0.76]) (37 of 69 evaluable patients; prevalence of 54%). In ovarian cancer, the definition of biomarker positive also required that patients have low ErbB2 (HER2) levels. In breast cancer, where only ErbB2 (HER2) negative patients were enrolled in the clinical trial, this requirement was not needed. In lung cancer, where ErbB2 (HER2) levels are naturally low, this requirement was also not needed.

Heregulin mRNA was measured in two different ways in the Phase 2 clinical trials. For archived tissue samples obtained through surgical removal of tumor tissue, which was the source of tissue in the breast cancer clinical trial, heregulin mRNA was measured by reverse transcriptase polymerase chain reaction (RT-PCR). This is a commonly used quantitative assay that provides a measure of the amount of heregulin mRNA in a block of tissue. In tissue samples obtained through a biopsy procedure, which was the source of tissue in the ovarian and lung cancer studies, heregulin mRNA was measured by RNA in situ hybridization (RNA-ISH). This is an assay in which a section of tissue is stained for heregulin mRNA and scored by a certified pathologist. Both of these assays have been transferred to certified diagnostic laboratories for use in future clinical trials of MM-121.

MM-111

MM-111 overview

MM-111 is a bispecific antibody designed to inhibit ErbB3 signaling in cancer cells that are characterized by overexpression of the ErbB2 (HER2) cell surface receptor. A bispecific antibody is a type of antibody that is able to bind simultaneously to two distinct target cell proteins or receptors. In the case of MM-111, these targets are the ErbB2 (HER2) receptor and the ErbB3 receptor. Our research and that of others suggest that the ErbB2 (HER2)

receptor triggers tumor growth and survival when it binds together with the ErbB3 receptor and another protein called heregulin. MM-111 is designed to anchor to both receptors, ErbB2 (HER2) and ErbB3, on the cell surface and block heregulin s ability to transmit tumor growth signals.

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We have evaluated the safety of MM-111 in combination with a range of therapies across ErbB2 (HER2) positive solid tumors, including gastric, esophageal, gastroesophageal junction, breast, ovarian and bladder cancers. In 2013, we obtained orphan drug designation in the United States for MM-111 for the treatment of gastric, esophageal and gastroesophageal junction cancers.

As discussed below, we have stopped enrollment into our Phase 2 clinical trial of MM-111 based on a recommendation from the DSMB for the clinical trial, which cited shorter PFS on the treatment arm relative to the control arm in the overall patient population. We do not plan to invest in additional development of MM-111 at this time.

MM-111 Phase 2 clinical trial

In 2013, we enrolled our first patient in a Phase 2 clinical trial of MM-111 for the treatment of advanced gastric, esophageal and gastroesophageal junction cancers. Overexpression of the ErbB2 (HER2) cell surface receptor has been reported in 7% 34% of gastric cancers. This Phase 2 clinical trial was designed to evaluate whether MM-111 is effective in gastric, esophageal and gastroesophageal junction cancer patients overexpressing the ErbB2 (HER2) receptor. The clinical trial enrolled patients who would traditionally receive trastuzumab-based therapy due to their ErbB2 (HER2) score of 3+ on the HercepTest®, or their ErbB2 (HER2) score of 2+ on the HercepTest® and their positive FISH status (FISH positive), and randomized those patients to receive either MM-111 in combination with paclitaxel and trastuzumab or paclitaxel and trastuzumab. In February 2015, we stopped enrolling patients in this clinical trial prior to full enrollment based on a recommendation from the DSMB for the clinical trial, which cited shorter PFS 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. A preliminary analysis shows that a vast majority of the patients in this clinical trial were below the threshold of heregulin levels that we believe are necessary to benefit from MM-111.

MM-111 companion diagnostic development

The current focus of our companion diagnostic development for MM-111 is the development of assays to quantify heregulin in patient samples from our clinical trials. We are testing additional quantitative assays for other biomarkers in archived and pretreatment patient biopsies from our clinical trials to generate data to support our biomarker hypotheses. This diagnostic is in preclinical development.

MM-151

MM-151 overview

MM-151 is an oligoclonal therapeutic consisting of a mixture of three fully human monoclonal antibodies designed to bind to non-overlapping epitopes of EGFR (ErbB1). An oligoclonal therapeutic is a mixture of two or more distinct monoclonal antibodies. EGFR (ErbB1) has long been recognized as an important drug target in several malignancies, including lung, breast, colon, pancreatic and head and neck cancers. We are conducting a Phase 1 clinical trial of MM-151 in patients with refractory solid tumors.

Based on our preclinical research, we believe that MM-151 may offer the following advantages over other EGFR (ErbB1) inhibitors:

MM-151 is designed to block the signal amplification that our research suggests occurs in the EGFR (ErbB1) pathway. Binding to multiple epitopes of EGFR (ErbB1) may result in superior signal inhibition compared to currently marketed EGFR (ErbB1) therapies, which only bind to one epitope.

MM-151 is designed to inhibit the signaling that results from the binding of a full range of EGFR (ErbB1) ligands. In contrast, currently marketed therapies block the signaling of only a subset of these ligands. As a result, a broader patient population may derive clinical benefit from MM-151.

Tumors treated with marketed monoclonal antibodies directed at EGFR (ErbB1), such as cetuximab and panitumumab, often develop resistance to these therapies. We hypothesize that this resistance often

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results from the production by the tumor of a different type of ligand that binds to EGFR (ErbB1). Because MM-151 is designed to block a full range of EGFR (ErbB1) ligands, resistance to treatment with MM-151 may be delayed or reduced compared to existing therapies.

We believe that there may be the potential to expand MM-151 into indications in which targeted EGFR (ErbB1) therapies are not currently approved, but which our preclinical research indicates should contain patients who will respond to these therapies. Potential indications include lung cancer, triple negative breast cancer and colorectal cancer.

MM-151 Phase 1 clinical trial

We are conducting a Phase 1 clinical trial of MM-151 as a monotherapy and in combination with irinotecan in patients with solid tumors. The Phase 1 clinical trial will assess the safety of MM-151 and determine the recommended Phase 2 dose. Four sites are participating in this trial.

MM-151 companion diagnostic development

We are focusing our diagnostic efforts for MM-151 on the identification of key biomarkers that will indicate which patient populations are likely to benefit from MM-151 treatment.

MM-141

MM-141 overview

MM-141 is a fully human tetravalent bispecific antibody designed to inhibit signaling of the PI3K/AKT/mTOR pathway initiated by the insulin-like growth factor 1 receptor, or IGF-1R, and ErbB3 cell surface receptors. A tetravalent bispecific antibody is a single molecule that has four binding sites, two for each of two different target cell surface receptors. PI3K/AKT/mTOR signaling is often activated in cancers in response to stress induced by chemotherapies or targeted anti-cancer medicines and is believed to play a significant role in promoting tumor cell survival. We are conducting a Phase 1 clinical trial of MM-141 as a monotherapy and in a combination therapy setting in patients with solid tumors. In 2014, we obtained orphan drug designation in the United States for MM-141 for the treatment of pancreatic cancer.

We designed MM-141 to suppress the PI3K/AKT/mTOR signaling pathway by reducing the levels of IGF-1R and ErbB3 receptor complexes that trigger the pathway. Based on our preclinical research, we believe that MM-141 may offer the following advantages compared to antibodies that solely target IGF-1R or ErbB3:

MM-141 is a tetravalent antibody that binds to both IGF-1R and ErbB3 with high affinity and avidity.

MM-141 is designed to block pro-survival signaling of major activators of PI3K/AKT/mTOR, such as heregulin, IGF-1 and IGF-2.

MM-141 is designed to block mutual compensation in IGF-1R and ErbB3 mediated activation of PI3K/AKT/mTOR by co-inhibiting both targets.

MM-141 is designed to degrade IGF-1R and ErbB3 containing receptor complexes that are commonly activated in tumors in response to PI3K/AKT/mTOR inhibition by a small molecule or an antibody.

MM-141 appears not to activate the immune system, which reduces the chance of off-target adverse events.

MM-141 Phase 1 clinical trial

We are conducting a Phase 1 clinical trial of MM-141 in both a monotherapy and a combination therapy setting in patients with solid tumors. This is a Phase 1 dose-escalation clinical trial evaluating safety and tolerability and pharmacokinetic and pharmacodynamic properties of MM-141 as a monotherapy and in

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combination with everolimus or with nab-paclitaxel and gemcitabine. The purpose of this trial is to assess the safety of MM-141 and identify the recommended Phase 2 dose. The monotherapy and combination of MM-141 with nab-paclitaxel and gemcitabine portions of this Phase 1 clinical trial are complete, and the combination of MM-141 with everolimus is ongoing. In the monotherapy arm, no dose-limiting toxicities were observed at any of the studied dose levels. In the nab-paclitaxel and gemcitabine combination arm, the observed safety profile of MM-141 in combination with nab-paclitaxel and gemcitabine was comparable to expected toxicities reported with the chemotherapy combination when used alone.

MM-141 Phase 2 clinical trial

We anticipate initiating a Phase 2 clinical trial of MM-141 in combination with nab-paclitaxel and gemcitabine in front-line pancreatic cancer in 2015.

MM-141 companion diagnostic development

We are conducting research and development on an *in vitro* companion diagnostic for MM-141 that will help to determine which patients will derive benefits from the drug alone or in combination with other therapies, while experiencing a satisfactory safety profile. This research is focused on identifying pathway-relevant biomarkers and assessing their correlation with the magnitude of patient response to MM-141. Thus far, we have identified serum-free IGF-1 as a useful stratification criteria and intend to use a proprietary, validated test to prospectively select patients with high serum-free IGF-1 levels for inclusion into the Phase 2 clinical trial of MM-141.

Preclinical Product Candidates

We are developing our preclinical product candidates for a range of solid tumor indications. Our most advanced preclinical candidates are MM-310, a targeted nanotherapeutic, and MM-131, a multispecific antibody.

Network Biology

Network Biology is what we call our proprietary systems biology-based approach to biomedical research. The goal of Network Biology is to understand how the complex molecular interactions that occur within cell signaling pathways, or networks, regulate cell decisions and how network dysfunction leads to disease. This platform utilizes proprietary, dynamic biological data generated in a high-throughput method in which we test multiple biological or chemical parameters using engineering, analytical and modeling expertise, and from which we build computational models of cell biology to further our drug discovery, design and predictive development. To execute Network Biology, we have developed an expertise in generating kinetic data, describing molecular changes or interactions over time, to illuminate the dynamic interactions that occur within biological systems. We apply Network Biology throughout the research and development process, including for target identification, lead compound design and optimization, diagnostic discovery, *in vitro* and *in vivo* predictive development and the design of clinical trial protocols.

Our models are constructed and validated using internally generated and proprietary data sets. Following the validation of a comprehensive model of a cell signaling network, we are able to use the model for drug discovery. Contrary to traditional methods, a significant portion of our discovery work takes place *in silico*, or using the model for simulation. We believe that this approach is more efficient and productive for drug discovery and development than traditional approaches.

As one example, we identified ErbB3, the target of MM-121, using our proprietary model of the ErbB signaling network after conducting a sensitivity analysis on its signaling process. Although the ErbB pathway has been

extensively targeted by cancer therapeutics, we believe that understanding the relative importance of the different components of the ErbB network is central to identifying an attractive drug target and a therapeutic

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directed at this target. In this case, we built a computational model of the ErbB signaling network that includes the most potent ErbB receptor ligands, as well as known and novel ErbB inhibitors. We populated the model with proprietary dynamic data that we generated from our experiments. The model describes in mathematical equations 700 biochemical reactions representing the ErbB signal transduction network, and identified ErbB3 as the key node in response to both ErbB3- and EGFR (ErbB1)-binding ligands. We then used this insight to develop MM-121.

Ultimately, we believe that Network Biology will result in better treatments for complex diseases by providing broader insight into disease and the potential therapeutic alternatives for physicians and patients. Using Network Biology, we are incorporating the identification of biomarkers and the development of companion diagnostics into the drug development process. We believe that integrated medicines may enable physicians to deliver the right drug to the right set of patients at the right time. This may improve patient outcomes by providing improved therapeutics along with the diagnostic information to guide physician treatment decisions, reduce the overall costs of treating and caring for cancer patients, and provide a basis for seeking favorable reimbursement of approved drugs from payors because of the benefits to patients.

In addition to improving patient care, we believe that Network Biology can increase the productivity of biomedical research, increase the probability of approval for new drugs and produce more precisely targeted therapeutics. We believe that our therapeutic oncology product candidates will have a greater probability of success than product candidates based on conventional drug development because Network Biology provides us with:

- a multidisciplinary, integrated approach to understanding complex biology;
- simulation and modeling capabilities that aid in the efficiency and productivity of development; and
- the capability to design and build a broad range of therapeutic product candidates without being limited to a particular drug design technology or target class.

Although our initial focus is oncology, we believe that our Network Biology approach is applicable to a broad range of therapeutic areas beyond cancer, including bone and joint conditions, infectious disease, inflammation, central nervous system disease and other areas of medicine with high unmet needs. While we may pursue some of these disease areas directly ourselves, because of the potential of very broad applicability of our Network Biology approach, our plan is to pursue many or all of these other areas through collaborations, licenses and other arrangements with third parties. As an example, in 2010, we established Silver Creek Pharmaceuticals, Inc., or Silver Creek, to apply our Network Biology approach to the research and development of regenerative medicines to repair the heart. Silver Creek is currently a majority owned subsidiary.

Therapeutic Design Capabilities

We apply the insights about cell signaling dynamics that we gain from Network Biology across a range of therapeutic technologies to design drug candidates that we believe can be efficiently delivered to the selected molecular target. We believe that the best therapies for the oncology indications that we are pursuing are targeted therapies that, in contrast with conventional chemotherapies, are highly selective for the molecular mechanisms that we are seeking to affect and, as a result, offer the potential for significant efficacy and safety benefits. Two such targeted therapies are human monoclonal antibodies and nanotherapeutics.

Human monoclonal antibodies

Human monoclonal antibodies are a key component of many of our targeted therapies based on their range of favorable attributes, including their significant target specificity and avidity relative to small molecules and their well understood pharmacokinetic properties. We have designed antibodies for use as stand-alone

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therapeutics and have incorporated antibodies into other therapeutics, such as targeted nanotherapeutics, as targeting or docking agents. We work with several antibody formats, including the following:

- Fully human recombinant monoclonal antibodies and fragments of fully human recombinant monoclonal antibodies that include the antibody binding domain. Monoclonal antibodies and antibody fragments are proteins that bind specifically to one defined site on a cell surface protein or receptor.

- Multispecific antibody formats, which are comprised of two or more antibodies or antibody fragments linked to a common scaffold molecule to produce a single molecule that specifically binds to distinct epitopes on two or more target cell surface proteins or receptors.

- Oligoclonal antibody mixtures, which are comprised of defined ratios of two or more recombinant human monoclonal antibodies that target two or more distinct epitopes on a single cell surface protein or receptor.

Nanotherapeutics

Our nanotherapeutics are lipidic particles carefully constructed to encapsulate active drug payloads. Nanoscale objects typically, though not exclusively, have dimensions on the order of 100 nanometers or smaller. We believe that nanotherapeutics offer the following potentially favorable attributes:

- The uniform sizing of our nanotherapeutics is intended to enable targeting and preferential deposition within tumors by taking advantage of the enhanced permeability and retention, or EPR, effect to selectively enter, and subsequently accumulate in, tumors with leaky vasculature.

- We formulate our nanotherapeutics to minimize the leakage of active drug payload out of the particle before the nanotherapeutic has reached the tumor, with the goal of limiting systemic exposure, and the associated occurrence of adverse events, and maximizing the amount of active drug that reaches the target.

- Encapsulation is designed to protect the active drug payload as it passes through the circulation and organs of the body, such as the liver, preventing premature clearance or metabolism of the active drug, and thereby extend the pharmacokinetic profile and enable more convenient dosing regimens.

- We can efficiently create targeted nanotherapeutics using our technical expertise and know-how that enable insertion of targeting agents, such as antibodies, into our nanotherapeutics.

- We can customize our nanotherapeutics for use with a variety of drug payloads, including chemotherapies, cytotoxics and nucleic acids, such as siRNA and genes.

Manufacturing

We manufacture bulk drug substance and bulk drug product for use in our clinical trials and research and development efforts for all of our therapeutic product candidates using current good manufacturing practices, or cGMP, at our approximately 13,500 square foot multi-product facility located at our corporate headquarters in Cambridge, Massachusetts. We have the capabilities to manufacture antibodies, nanotherapeutics and antibody-targeted nanotherapeutics.

The biologic suite in our facility is comprised of multiple independent clean rooms, includes single-use bioreactors, and is sized to be able to produce sufficient material to meet the demands of our planned and ongoing Phase 1 and Phase 2 clinical trials. The nanoliposome suite in our facility is also comprised of multiple classified clean rooms and has been designed to comply with current FDA and EMA cGMPs for the manufacture of clinical and commercial bulk drug product. As of January 31, 2015, we employed approximately 89 employees in manufacturing activities.

We believe that our strategic investment in manufacturing capabilities allows us to advance product candidates at a more rapid pace and with more flexibility than a contract manufacturer, produce drug substance in a cost-effective manner while retaining control over the process and prioritize the timing of internal programs.

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Our manufacturing capabilities encompass the full manufacturing process through quality control and quality assurance and are integrated with our project teams from discovery through development. This structure enables us to efficiently transfer research stage lead molecules into manufacturing. We have designed our manufacturing facility and processes to provide maximum flexibility and rapid changeover for the manufacture of different product candidates. We outsource fill-finish, packaging, labeling and shipping.

We manufacture our antibody and nanotherapeutic product candidates using commercially available raw materials and well established manufacturing procedures. We produce antibodies in bioreactors using Chinese hamster ovary cells that have been genetically engineered to secrete our antibody. We then purify the antibodies using industry standard methods, which include affinity chromatography and ultrafiltration operations. We produce nanotherapeutics using high pressure filter extrusion of a mixture of cholesterol and lipids. We then load the nanoliposomes with active pharmaceutical ingredient using a proprietary process.

We have designed a commercial manufacturing process of MM-398 in our nanoliposome manufacturing suite, which we used to perform process validation runs. This commercial process will be filed within the chemistry manufacturing and controls section of our NDA for MM-398. The MM-398 manufactured from our commercial process can be used for both clinical trials and commercial sales. Additionally, we expect that we will enter into commercial supply agreements for us to supply MM-398 bulk product to our commercialization and development partners, Baxter and PharmaEngine.

For our antibody product candidates, we intend to continue to manufacture most bulk drug substance for preclinical testing and Phase 1 and Phase 2 clinical development at our current facility, except for MM-121 which is currently manufactured by a contract manufacturing organization. Our long term plan is to establish our own facilities for manufacturing antibody drug substance for Phase 3 clinical development and commercial sale. Pending our establishment of these facilities, we expect to transfer Phase 3 and commercial antibody manufacturing to a contract manufacturing organization. For our nanotherapeutic product candidates, we intend to continue to manufacture bulk drug product for preclinical testing and all stages of clinical development and initially manufacture bulk drug product for commercial sale at our current facility.

We are developing and testing diagnostic assays for predictive biomarkers in an internal laboratory under Good Clinical Laboratory Practices and through collaborations with third party vendors. Upon completion of the development of the diagnostic tests, we plan to evaluate external as well as internal options for manufacturing and commercialization of the tests.

We are leveraging our manufacturing capabilities to manufacture drug product on behalf of a third-party pharmaceutical company, and may enter into additional agreements to do so in the future. In 2013, we entered into an agreement with Watson Laboratories, Inc., or Actavis, as more fully described below, pursuant to which we will utilize our nanoliposomal manufacturing capabilities to develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection to Actavis. Under this agreement, we have also agreed to develop additional products for Actavis, the identities of which will be mutually agreed upon in the future.

Sales and Marketing

We have initiated an NDA submission with the FDA for MM-398, our lead product candidate, and are in the process of building our sales, marketing, reimbursement and product distribution infrastructure. Subject to receiving marketing approval, we expect to commence MM-398 commercial activities in the United States by building a focused sales and marketing organization. Outside of the United States, Baxter has exclusive commercialization rights for all potential indications of MM-398 worldwide with the exception of Taiwan, and PharmaEngine has exclusive

commercialization rights in Taiwan.

We believe our commercialization partners for MM-398 possess the relevant expertise to launch MM-398 outside of the United States, pending receipt of marketing approval in the applicable territories. For instance, Baxter has demonstrated the ability to successfully launch innovative products, penetrate oncology markets and

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drive the growth of multiple brands in highly competitive markets. Complementing Baxter s expertise, we are building commercial capabilities in the United States across sales, marketing, reimbursement and distribution activities. We are developing a deep understanding of oncology customers, and we intend to utilize this knowledge to develop relevant educational content to support the introduction of MM-398 as a potential treatment for patients with metastatic pancreatic cancer who have been previously treated with gemcitabine.

We expect that in the United States, our sales and marketing organization that supports MM-398 could form the basis of the sales and marketing organization that we would use to sell our other products, subject to receiving marketing approval for those other products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating solid tumors, including the lung, breast, ovarian, pancreatic, colorectal and gastric cancers for which our product candidates are being developed. Outside the United States, we expect to either enter into distribution and other marketing arrangements with third parties for any of our other product candidates that obtain marketing approval, or we may expand our sales and marketing organization to support such territories ourselves.

We are building a marketing organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with thought leaders in relevant fields of medicine.

We plan to tightly integrate the marketing of our therapeutics and companion diagnostics, subject to receipt of marketing approval. As we expect to pair various types of diagnostics with our therapeutics, it is likely that the sales and marketing tactics and business model employed for our various diagnostics may differ from one another.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our Network Biology technologies, integrated research, clinical and manufacturing capabilities, development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors may 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. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less

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expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected because in many cases insurers or other third-party payors seek to encourage the use of generic products. There are many generic products currently on the market for the indications that we are pursuing, and additional products are expected to become available on a generic basis over the coming years. If our therapeutic product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

The initial focus of our business is to develop therapeutics and companion diagnostics for the treatment of solid tumor cancers. Cancer is the second most common cause of death in the United States, exceeded only by heart disease, and accounts for almost one of every four deaths in the United States. There are a variety of available drug 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. In general, although there has been considerable progress over the past few decades in the treatment of solid tumors and the currently marketed therapies provide benefits to many patients, these therapies all are limited to some extent in their efficacy and frequency of adverse events, and none of them are successful in treating all patients. As a result, the level of morbidity and mortality from solid tumor cancers remains high.

The following table sets forth information about the incidence and selected treatments for some of the solid tumor cancers for which we are developing therapeutic product candidates and companion diagnostics. The U.S. estimated annual incidence is based on information from the American Cancer Society, *Cancer Fact & Figures 2015*.

Tumor Type	U.S. Annual Incidence	Selected Marketed Therapies
Breast	234,190	trastuzumab (Herceptin®); docetaxel (Taxotere®); paclitaxel (Taxol®, Abraxane®); capecitabine (Xeloda®); tamoxifen (Nolvadex®, Soltamox®); anastrazole (Arimidex®); letrozole (Femara®); exemestane (Aromasin®); ado-trastuzumab emtansine (Kadcyla®); pertuzumab (Perjeta®); everolimus (Afinitor®); palbociclib (Ibrance®)
Lung and bronchus	221,200	ceritinib (Zykadia); docetaxel (Taxotere); gemcitabine (Gemzar®); pemetrexed (Alimta®); gefitinib (Iressa®); erlotinib (Tarceva®); bevacizumab (Avastin®); paclitaxel (Taxol, Abraxane)
Colorectal	132,700	oxaliplatin (Eloxatin®); irinotecan (Camptosar®); bevacizumab (Avastin); cetuximab (Erbitux®); panitumumab (Vectibix®); ziv-aflibercept (Zaltrap®)
Pancreatic	48,960	nab-paclitaxel (Abraxane); gemcitabine (Gemzar); erlotinib (Tarceva)
Liver	35,660	sorafenib (Nexavar®)
Brain and other nervous system cancers	22,850	temozolomide (Temodar®); carmustine (BiCNU®); polifeprosan 20 with carmustine implant (Gliadel®); bevacizumab (Avastin)
Gastric	24,590	ramucirumab (Cyramza®); capecitabine (Xeloda); trastuzumab (Herceptin); docetaxel (Taxotere); oxaliplatin (Eloxatin); epirubicin

		(Ellence®)
Ovarian	21,290	olaparib (Lynparza); liposomal doxorubicin (Doxil); bevacizumab (Avastin); paclitaxel (Taxol, Abraxane); gemcitabine (Gemzar)

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In addition to the marketed and generic therapies for solid tumors, there are also a number of products in late stage clinical development to treat solid tumors. These products in development may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain market approval.

Collaboration and License Agreements

We are party to a number of collaboration agreements for the development and commercialization of our product candidates and license agreements under which we license patents, patent applications and other intellectual property. We consider the following collaboration and license agreements to be material to our business.

Baxter

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

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

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

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

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

licensed patent rights.

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PharmaEngine

In May 2011, we entered into an assignment, sublicense and collaboration agreement with PharmaEngine, or the PharmaEngine agreement. Under the agreement, PharmaEngine assigned to us its rights and obligations under a 2005 agreement with Hermes BioSciences, Inc., or Hermes, to develop and commercialize MM-398 in Europe and certain countries in Asia. Through our acquisition of Hermes in 2009, we held the rights to MM-398 in North America and the rest of the world. PharmaEngine also granted to us an exclusive right and license, with the right to sublicense, under PharmaEngine technology and rights to develop and commercialize MM-398 worldwide outside of Taiwan. We granted to PharmaEngine a paid-up, royalty free, exclusive right and license under our technology and rights to develop and commercialize MM-398 in Taiwan. Upon entering into the PharmaEngine agreement, we paid PharmaEngine a $10.0 million upfront license fee. In addition, we made a milestone payment of $5.0 million to PharmaEngine in connection with dosing the first patient in our Phase 3 clinical trial of MM-398, which occurred and was paid in the first quarter of 2012.

In September 2014, we amended the PharmaEngine agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that we are required to pay to PharmaEngine. As a result of this amendment, we made a $7.0 million milestone payment to PharmaEngine. Additionally, as a result of this amendment, a previously contingent $5.0 million milestone payment is now payable to PharmaEngine upon the earlier of either the FDA s acceptance of an NDA for MM-398 or April 30, 2015. Prior to the amendment of the PharmaEngine agreement, this milestone payment was contingent upon the award of certain specified regulatory designations.

Since entering into the PharmaEngine agreement, we have paid PharmaEngine an aggregate of $22.0 million in upfront license fees and milestone payments, with an additional $5.0 million contractually obligated in 2015. In addition to these amounts, we will also be required to pay PharmaEngine up to an additional $70.0 million in aggregate regulatory milestones, including $11.0 million of expected milestones to be paid in 2015, and $130.0 million in aggregate sales milestones, in each case with respect to Europe and certain countries in Asia. Under the agreement, PharmaEngine is entitled to tiered royalties based on net sales of MM-398 in Europe and certain countries in Asia. The royalty rates under the agreement range from high single digits up to the low teens as a percentage of our net sales of MM-398 in these territories. Our obligation to pay royalties to PharmaEngine continues on a country-by-country basis until ten years after the first commercial sale of MM-398 in such country. We are responsible for the development and commercialization, and all related costs and expenses, of MM-398 in all countries except Taiwan, where PharmaEngine retains the right to develop and commercialize MM-398 at its expense. Each party has agreed to use commercially reasonable efforts to develop, in accordance with a development plan, and commercialize MM-398 in its respective territory. We also have a diligence obligation to initiate a second Phase 3 clinical trial of MM-398 in a different solid tumor indication within a timeframe specified in the agreement.

Multiple executive committees were formed under the PharmaEngine agreement, each comprised of an equal number of representatives from each party. The steering committee is responsible for reviewing and approving changes to the development plan, providing overall strategic direction with respect to development of MM-398 under the development plan and overseeing other committees. The steering committee is also responsible for resolving any disputes arising under the agreement at the steering committee or that are referred to it by any of the other committees. If a matter is unresolved by the steering committee, it may be referred for resolution to executive officers from both companies. We have final decision making authority on any such matter not resolved by the executive officers that relates to the worldwide development of MM-398 or commercialization of MM-398 outside of Taiwan. The development committee is responsible for recommending to the steering committee changes to the development plan and overseeing the progress of the development program and monitoring the parties compliance with their respective obligations under the development plan.

Upon expiration of all royalty and other payment obligations due to PharmaEngine under this agreement on a country-by-country basis, the licenses granted under the agreement will be deemed to be perpetual, fully paid-up and irrevocable with respect to the licensed product in such country. Either party may terminate the agreement in the event of an uncured material breach by the other party. In addition, we may terminate the agreement for

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convenience upon 90 days prior written notice. If PharmaEngine terminates this agreement in its entirety or with respect to Europe or the Asian territories because of our material breach, or if we terminate the agreement for convenience with respect to Europe or the Asian territories, then we are required to grant PharmaEngine a license under our technology and rights with respect to MM-398 in Europe or the Asian territories, as applicable, and PharmaEngine is required to pay us single-digit royalties for net sales of MM-398 in such territories.

Actavis

In November 2013, we entered into a development, license and supply agreement with Actavis, or the Actavis agreement, pursuant to which we will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection, or initial product, to Actavis, which Actavis will process into finished product and commercialize globally. We also agreed to develop additional products for Actavis, the identities of which will be mutually agreed upon in the future. We are eligible to receive up to $15.5 million under the Actavis agreement, including $2.0 million upfront and the remainder in development funding and development, regulatory and commercial milestone payments related to the initial product. We will also receive a double digit percentage of net profits on global sales of the initial product and any additional products. We will manufacture and supply the initial product to Actavis in bulk form at an agreed upon unit price. In January 2015, we amended the Actavis agreement to transfer certain responsibilities from us to Actavis in exchange for reducing the aggregate milestone payments that we are eligible to receive by $0.4 million.

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

Dyax

In January 2007, we entered into an amended and restated collaboration agreement with Dyax Corp., or Dyax, which superseded a prior collaboration agreement with Dyax that we entered into in December 2005. Under this collaboration agreement, Dyax uses its proprietary phage display technology to identify antibodies that bind to targets of interest to us as therapeutics or diagnostics. Further, Dyax has granted to us a worldwide, non-exclusive, royalty free right to use and make any and all of the antibodies identified by Dyax for certain research purposes. In order to clinically develop or commercialize any such antibody, however, we must obtain an additional product license from Dyax on a target-by-target basis. We have the option to obtain one or more product licenses on terms set forth in the collaboration agreement, subject to limitations on the availability of each such product license under an agreement between Dyax and Cambridge Antibody Technologies, which has merged with MedImmune, LLC and is now owned by AstraZeneca PLC.

As consideration for the grant of the initial research license, we paid Dyax a research fee based on the total estimated full time equivalent researchers that were required to conduct the research plan and a fee for achieving certain technical milestones. If we elect to obtain a product license with respect to any therapeutic or diagnostic target, we are required to pay to Dyax an additional upfront license fee for the applicable antibody. We also will be required to make additional maximum aggregate development and regulatory milestone payments of $16.2 million for therapeutic products and maximum aggregate regulatory milestone payments of $1.0 million for diagnostic products directed to selected targets. In addition, Dyax is entitled to mid single digit royalties based on net sales of products covered by any product license that we obtain from Dyax. Our obligation to pay royalties to Dyax continues on a product-by-product and country-by-country basis until the later of a specified number of years after the first

commercial sale of the product in such country and the expiration of the patent rights covering the product in such country. MM-121 and a component of MM-141 were identified under this agreement, and we have obtained the required target licenses from Dyax by exercising our product license options and paying the applicable license fees. We are obligated to use commercially reasonable efforts to develop and commercialize the antibodies for which we obtain a commercial license.

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This agreement will remain in effect, unless terminated earlier, for so long as we or any of our affiliates or sublicensees continue to develop or commercialize products that remain royalty-bearing under the agreement. Either party may terminate the agreement in the event of an uncured material breach by the other party. We also may terminate the agreement in its entirety or on a product-by-product basis at any time upon 90 days prior written notice.

Adimab

In November 2009, we entered into a collaboration agreement with Adimab LLC, or Adimab, to allow us to evaluate the utility of using antibodies identified during the collaboration as therapeutics or diagnostics. Under the agreement, Adimab granted to us a worldwide, non-exclusive, royalty free right to use materials provided by Adimab to perform non-clinical research during the evaluation term. Adimab also granted to us an option to obtain the assignment of specified patent rights claiming the selected antibodies and a license under Adimab s background patent rights and know-how for the development and commercialization of the antibodies.

As partial consideration for the research license grant, we paid Adimab a technology access fee at the time of grant, research fees based on the total estimated full time equivalent researchers that were required to conduct the research plan and a fee for achieving certain technical milestones. We have exercised our assignment and license option by paying Adimab a fee of $1.0 million. In addition, we are required to pay Adimab up to an aggregate of $13.5 million per therapeutic area, for the first four therapeutic areas, upon achievement of specified development and regulatory milestones, of which we have paid $1.5 million with respect to the first therapeutic area, and up to an aggregate of $500,000 per diagnostic product upon the achievement of specified regulatory milestones. In addition, Adimab is entitled to mid single digit royalty payments based on net sales of therapeutic products and diagnostic products arising from the collaboration. Our obligation to pay royalties to Adimab continues on a product-by-product and country-by-country basis until the later of a specified number of years after the first commercial sale of the product in such country and the expiration of the patent rights covering the product in such country, provided that the royalty term will not extend beyond a specified number of years after the first commercial sale of the product in such country. We are obligated to use commercially reasonable efforts to develop and commercialize at least one product that incorporates the antibodies for which we exercised our assignment and license option in each of the United States, Europe and Japan. MM-151 was generated under this agreement.

The term of the agreement expires on a country-by-country basis on the earliest date after which no payments are due to Adimab, unless earlier terminated. Either party may terminate the agreement in the event of an uncured material breach by the other party. In addition, we may terminate the agreement at any time upon 90 days prior written notice.

University of California

2005 agreement

In March 2005, we entered into a license agreement with The Regents of the University of California, or the Regents. Under the agreement, the Regents granted to us a royalty-bearing right and license in the United States and other countries where the Regents have the right to grant the license under certain patent rights and rights in biological materials to develop and commercialize products for therapeutic or diagnostic use in humans that are covered by the licensed patents. Licensed products under this agreement include MM-111. This license is exclusive with respect to certain patents, including some relevant to MM-111, and non-exclusive with respect to other patents and biological materials. The agreement requires that we diligently pursue the development, manufacture and commercialization of licensed products. In addition, we are required to meet specific development, regulatory and commercialization milestones within timeframes specified in the agreement. We have sole responsibility for the development and commercialization of products under the licensed technology. However, the agreement provides that the Regents may

require us to sublicense our exclusive rights for the

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application or use of licensed products covered by any exclusively licensed technology that we are not currently pursuing.

We are required to pay to the Regents an annual license maintenance fee of between $20,000 and $30,000 until the first commercial sale of a licensed product and are responsible for all development costs. In addition, we are required to pay to the Regents up to an aggregate of $725,000 per therapeutic product, other than the second therapeutic product, for which we are responsible for up to an aggregate of $906,250, based on the achievement of specified development and regulatory milestones. The Regents are also entitled to royalties in the low single digits based on net sales of products covered by the licensed technology. A minimum annual royalty is due to the Regents commencing in 2015. The minimum annual royalty increases from $100,000 in the first year it is payable to $500,000 in the fifth year and thereafter for the life of the patents. If we sublicense the rights granted to us under the licensed technology to a third party, then we are also obligated to pay to the Regents a portion of the sublicensing income related to the licensed technology.

If not terminated earlier, this agreement terminates upon the later of nine years from the market introduction of the last licensed product that contains the licensed biological materials or the expiration of all patent rights licensed under this agreement. At such time, we will have a perpetual, fully paid, world-wide, non-exclusive license. The Regents may terminate the agreement in the event of an uncured material breach by us. We may terminate the agreement on a country-by-country basis at any time upon 60 days prior written notice.

2000 agreement

In November 2000, we entered into a separate exclusive license agreement with the Regents. Under the agreement, the Regents granted us a royalty-bearing world-wide right and license under certain patent rights for the development and commercialization of products that are covered by the licensed patent rights, including MM-302. The agreement requires that we diligently pursue the development, manufacture and commercialization of licensed products. In addition, we are required to meet specified development, regulatory and commercialization milestones within timeframes specified in the agreement. We have the sole responsibility for the development and commercialization of products under the licensed technology.

We are required to pay to the Regents an annual license maintenance fee of $95,000 until the first commercial sale of a licensed product. We also are responsible for all development costs and have agreed to spend a minimum of $150,000 per year for such costs. In addition, we are responsible for up to an aggregate of $700,000 per product upon the achievement of specified development and regulatory milestones. The Regents are also entitled to royalties in the low single digits based on net sales of products covered by the licensed technology. If we sublicense the rights granted to us under the licensed technology to a third party, then we are also obligated to pay to the Regents a portion of the sublicensing income related to the licensed technology.

If not terminated earlier, this agreement terminates upon the expiration or abandonment of all patents licensed under this agreement. The Regents may terminate the agreement in the event of an uncured material breach by us. We may terminate the agreement on a country-by-country basis at any time upon 60 days prior written notice.

Intellectual Property

We aggressively strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and processes for their manufacture, as well as our diagnostic and drug discovery technologies and any other inventions that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our

business that are not amenable to, or that we do not consider appropriate for, patent protection, such as our proprietary network modeling programs and large scale protein and liposome production methods.

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Our success will significantly depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions once the experimental data necessary for an application become available. We generally file international applications under the Patent Cooperation Treaty, or PCT, within one year after the filing of a U.S. provisional application.

As of January 31, 2015, we owned 19 issued U.S. patents, one allowed U.S. patent application, five issued European patents and 51 issued patents and seven allowed patent applications in other jurisdictions, as well as 38 pending U.S. provisional and non-provisional patent applications and 240 pending foreign patent applications in Europe and other jurisdictions. As of January 31, 2015, we also co-owned one U.S. pending patent application and one issued and 31 pending foreign patent applications with Sanofi, as well as one issued U.S. patent, one pending U.S. non-provisional and seven foreign patent applications with Silver Creek. As of January 31, 2015, we had licenses to 38 U.S. patents and two pending U.S. patent applications, as well as numerous foreign counterparts to many of these patents and patent applications. Of these licensed patents and patent applications, we license the majority on an exclusive basis, with the rest licensed non-exclusively to us. The exclusive licenses are, in some cases, limited to certain technical fields, for example for medical and diagnostic purposes.

The patent portfolios for our six most advanced product candidates as of January 31, 2015 are summarized below.

MM-398

Our MM-398 patent portfolio is wholly owned by us and includes five issued U.S. patents covering the composition of and methods of making and using MM-398, all of which expire or, if issued, will expire in 2025, except for two U.S. patents that expire in 2028. Fifteen related international patent applications have issued or been allowed, and 11 are pending in Europe and a number of other countries. These international patents and patent applications, if issued, will expire in 2025. Our MM-398 portfolio further includes one pending PCT dosage and administration patent application that is eligible for worldwide filings that, if issued, will expire in 2033, and one pending U.S. provisional application that will be used to establish a non-provisional application that, if issued, will expire in 2035.

MM-302

Our MM-302 patent portfolio includes one wholly owned pending U.S. non-provisional application and nine foreign dosage and administration patent applications that, if issued, will expire in 2031; one pending diagnostic application that is pending in the United States, Europe and five other countries that, if issued, will expire in 2033; three PCT applications (two combination therapy and one diagnostic) that remain eligible for worldwide filings that, if issued, will expire in 2033 or 2034; and one U.S. provisional combination therapy application that may be used to establish non-provisional applications that, if issued, will expire in 2034. This portfolio also includes the following exclusively licensed issued U.S. patents:

two composition of matter patents that expire in 2019; and

one method of use patent and one allowed method of use patent application that expire in 2019.

In addition, this portfolio includes the following exclusively licensed European patents:

a composition of matter patent that expires in 2019; and

a composition of matter and method patent that expires in 2019.

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Our licensed MM-302 patent portfolio further includes several foreign composition of matter patents and patent applications that expire or, if issued, will expire between 2015 and 2017.

All of the licensed patents and patent applications related to MM-302 are licensed from the Regents.

MM-121

Our MM-121 patent portfolio is wholly owned by us, with the exception of:

- one method of use application that has been filed in the United States and 26 foreign jurisdictions worldwide, which is co-owned with Sanofi and, if issued, will expire in 2032; and

- one family of U.S. patents broadly covering anti-ErbB3 antibodies, the last of which will expire in 2016, that are licensed non-exclusively from the U.S. Public Health Service, a division of the U.S. Department of Health and Human Services.

Our wholly owned MM-121 portfolio includes two U.S. composition of matter patents, one allowed and 13 issued foreign patents, and one allowed and one other pending U.S. patent application. In foreign jurisdictions, one related patent is issued in Europe and 12 other jurisdictions, and one application is issued in three foreign jurisdictions and pending in Europe and 14 other jurisdictions; these expire or, if issued, will expire in 2028.

Pending method of use and diagnostic patents in this portfolio also include:

- one PCT application that is eligible for worldwide filings that, if issued, will expire in 2034;

- one U.S. and 17 foreign patent applications that, if issued, will expire in 2032;

- one issued U.S. patent, one pending U.S. patent application, two issued and two allowed foreign patents, and 15 foreign patent applications that, if issued, will expire in 2031; and

- two issued U.S. patents and one pending U.S. patent application, related issued foreign patents in Europe and seven other jurisdictions, and related pending foreign applications in eight other jurisdictions that, if issued, will expire in 2029.

MM-111

Our MM-111 patent portfolio includes two wholly owned, issued U.S. patents and seven pending U.S. patent applications covering the composition of, and method of use and diagnostics for, MM-111 that, if issued, will expire between 2029 and 2035. This portfolio also includes one PCT application that remains eligible for worldwide filings that, if issued, will expire in 2033. This portfolio also includes six issued related patents and 58 patent applications pending in Europe and a number of other jurisdictions that, if issued, will expire between 2028 and 2033. This portfolio also includes a pending provisional patent application that will be used as the basis of a PCT application that

will be eligible for worldwide filings that, if issued, will expire in 2035.

In addition, this portfolio includes the following patents licensed from the Regents:

- an exclusively licensed family of patents and patent applications that expire or, if issued, will expire in 2023, including three issued and one allowed U.S. composition of matter patents, a pending European divisional application, an issued European composition of matter patent that has been validated in 11 European Patent Organization countries, one allowed and three issued foreign patents and related applications pending in a number of other countries; and

- a non-exclusively licensed family of patents that expire in 2016, including granted U.S. and European composition of matter patents.

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MM-151

Our MM-151 patent portfolio is wholly owned and includes one U.S. and 12 foreign patent applications (one allowed) covering compositions, methods of use and diagnostics that is eligible for worldwide filings that, if issued, will expire in 2032. This portfolio also consists of two pending U.S. composition of matter and method of use patent applications and 13 related pending foreign applications that, if issued, will expire in 2031, and one issued and one pending U.S. and a related pending European diagnostic patent application that, if issued, will expire in 2032. This portfolio also includes two pending dosage and administration provisional applications that will be used as the basis of a single PCT application that will be eligible for worldwide filings that, if issued, will expire in 2035.

MM-141

Our MM-141 patent portfolio is wholly owned and consists of four pending patent applications. One of these pending patent applications covers the principle and methods of co-targeting IGF-1R and ErbB3 in human disease and is pending in the US, Europe, Canada, Australia and Japan, and if issued will expire no sooner than 2030. A second patent family covering compositions, methods of use, and disease indications has an issued U.S. patent, a pending U.S. patent application, an issued Japanese patent, and is pending in Europe and 12 other foreign jurisdictions. These patents and patent applications expire, or will expire, no sooner than 2032. A third application is pending in the United States, Europe, and nine other jurisdictions and covers compositions, methods of use, disease indications and drug combination regimens related to MM-141, and if issued will expire no sooner than 2033. A fourth pending application is in the form of five U.S. provisional patent applications that will be used as the basis of a single international application that will be eligible for worldwide filings that, if issued, will expire in 2035.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug, biological product or medical device approved pursuant to a pre-market approval, or PMA, may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an extension and only those claims reading on the approved drug are extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors, including those involved in the filing of an NDA or a biologics license application, or BLA.

We are currently engaged in a single material ongoing opposition proceeding to a European patent in the European Patent Office to narrow or invalidate the claims of a patent owned by a third party. For more information, see Part I, Item 3. Legal Proceedings of this Annual Report on Form 10-K. We have obtained a favorable interim decision in this opposition, which is now under appeal. The ultimate outcome of this opposition remains uncertain.

We rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our

employees, consultants, scientific advisors and contractors. We also seek to preserve the

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integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Silver Creek

In August 2010, we acquired 12,000,000 shares of Series A preferred stock of Silver Creek, a newly formed company, in exchange for our grant to Silver Creek of technology licenses. We granted to Silver Creek a royalty free license under certain antibody growth factor patent rights to develop and commercialize products covered by the licensed patent rights. This license is exclusive to Silver Creek for therapeutic or diagnostic use in humans for the promotion of organ regeneration and co-exclusive with us for all other uses. We also granted to Silver Creek royalty free, non-exclusive licenses under certain patent rights and know-how to use certain of our technologies for research and development purposes. Either party may terminate the agreement in the event of an uncured material breach by the other party.

In August and December 2010, Silver Creek issued and sold an aggregate of 4,189,904 additional shares of its Series A preferred stock at a price per share of $1.00 to other investors for an aggregate purchase price of $4,189,904. In addition, on December 21, 2012, Silver Creek entered into a Note Purchase Agreement pursuant to which it issued convertible notes to various lenders, which did not include us, in aggregate principal amounts of $1.6 million in December 2012, $0.3 million in February 2013 and $0.6 million in December 2013. The convertible notes bore interest at 6%. The notes matured and converted, along with an immaterial amount of accrued interest, into 2,603,281 shares of Silver Creek Series A preferred stock on December 31, 2013. During the year ended December 31, 2014, Silver Creek issued convertible notes to various lenders, which did not include us, in aggregate principal amounts of an additional $1.0 million. The convertible notes bore interest at 6% and matured and converted, along with an immaterial amount of accrued interest, into approximately 1.0 million shares of Silver Creek Series A preferred stock on December 31, 2014. As of January 31, 2015 and 2014, we owned approximately 60% and 64%, respectively, of the outstanding capital stock of Silver Creek, making Silver Creek a majority owned subsidiary.

Silver Creek is applying our Network Biology approach to the research and development of regenerative medicines to repair the heart. In the future, we may consider forming additional businesses or business units to apply our Network Biology approach to multiple additional disease areas outside the oncology field. We expect to do so in some cases, as with Silver Creek, through the establishment of separately funded companies.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, biological products and medical devices, such as those we are developing.

United States drug and biological product approval process

In the United States, the FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply

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with the applicable United States requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA s refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, civil penalties and criminal prosecution.

The process required by the FDA before a drug or biological product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA s good laboratory practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug or biological product for each indication;
- submission to the FDA of an NDA or BLA, as applicable;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity; and
- FDA review and approval of the NDA or BLA.

We expect that all of our clinical product candidates, other than MM-398, will be subject to review as biological products under BLA standards. We expect that MM-398 will be subject to review as a drug under NDA standards. MM-302 contains both drug and biological components. We believe that this combination product will be subject to review as a biological product, pursuant to a BLA. However, it is possible that the FDA could consider MM-302 subject to review pursuant to an NDA.

Preclinical studies

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases to establish a rationale for therapeutic use. The

conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed protocol for clinical studies, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical trials

Clinical trials involve the administration of the investigational new drug to human subjects healthy volunteers or patients under the supervision of qualified investigators in accordance with GCP requirements,

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which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The drug or biological product is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, side effects associated with increasing doses, pharmacological action, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The drug or biological product is administered to a limited patient population to identify common adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The drug or biological product is administered to an expanded patient population in adequate and well-controlled clinical trials, typically at geographically dispersed clinical trial sites, to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to permit the FDA to evaluate the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB s requirements or if the drug has been associated with unexpected serious harm to patients.

Disclosure of clinical trial information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public on the ClinicalTrials.gov website as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Marketing approval

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product s pharmacology chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. FDA approval of the NDA or BLA is

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required before marketing of the product may begin in the United States. Under federal law, the submission of most NDAs and BLAs is additionally subject to a substantial application user fee, currently exceeding $2,335,200, and the sponsor of an approved NDA or BLA is also subject to annual product and establishment user fees, currently exceeding $110,370 per product and $569,200 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of all NDAs and BLAs within the first 60 days after receipt before accepting them for filing based on the agency s threshold determination that they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs and BLAs. Most such applications for non-priority products are reviewed within ten to twelve months after filing, and most applications for priority review products, that is, drugs and biologics that the FDA determines represent a significant improvement over existing therapy, are reviewed in six to eight months after filing. The review process may be extended by the FDA for three additional months to consider certain late-submitted information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or biological products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval process requires substantial time, effort and financial resources, and each may take many years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our product candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

After the FDA s evaluation of the NDA or BLA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug or biological product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug s safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, which can materially affect the potential market and

profitability of the product. The FDA may prevent or limit further marketing of a product

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based on the results of post-market studies or surveillance programs. After approval, some types of changes to the approved product, such as changes in indications, manufacturing changes and labeling, are subject to further testing requirements and FDA review and approval.

Fast track designation

The FDA is required to facilitate the development and expedite the review of drugs and biologics that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new drug or biologic candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days after receipt of the sponsor s request.

In addition to other benefits, such as the ability to use surrogate endpoints and have greater interactions with the FDA, the FDA may initiate review of sections of a fast track product s NDA or BLA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA s time period goal for reviewing a fast track application does not begin until the last section of the NDA or BLA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority review

Under FDA policies, a product candidate may be eligible for priority review, or review within a six to eight month time frame from the time a complete application is accepted for filing. Products regulated by the FDA s Center for Drug Evaluation and Research, or CDER, are eligible for priority review if they provide a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. Products regulated by the FDA s Center for Biologics Evaluation and Research are eligible for priority review if they provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. A fast track designated product candidate would ordinarily meet the FDA s criteria for priority review.

Accelerated approval

Under the FDA s accelerated approval regulations, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based on a surrogate endpoint that is reasonably likely to predict clinical benefit. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough therapy designation

The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that

the drug may demonstrate substantial improvement over existing therapies on one or more

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clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor s request.

Orphan drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologics intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug or biologic for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application user fee.

Pediatric information

Under the Pediatric Research Equity Act of 2003, an NDA, BLA or supplement to an NDA or BLA must contain data that are adequate to assess the safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Under the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA has additional authority to take action against manufacturers not adhering to pediatric study requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation.

The Hatch-Waxman Act

Abbreviated new drug applications

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant s product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the

original listed drug.

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The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book. Specifically, the applicant must certify that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product s listed patents or that such patents are invalid is called a Paragraph IV certification. If the ANDA applicant does not challenge the listed patents, the ANDA will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA also will not be approved until any applicable non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients during which ANDAs for generic versions of those drugs cannot be received by the FDA unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and thus, no ANDA may be filed before the expiration of the exclusivity period. Federal law provides for a period of three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor, during which the FDA cannot grant effective approval of an ANDA based on that listed drug. Under the Best Pharmaceuticals for Children Act, or BPCA, federal law also provides that periods of patent and non-patent marketing exclusivity listed in the Orange Book for a drug may be extended by six months if the NDA sponsor agrees to conduct and report on pediatric studies identified by the FDA in a written request within the statutory timeframes. Applications under the BPCA are treated as priority applications, with all the benefits that designation confers.

Patent term extension

After NDA approval, owners of relevant drug patents may apply for up to a five year patent term extension. The allowable patent term extension is calculated as half of the drug s testing phase, based on the time between IND application and NDA submission, and all of the review phase, based on the time between NDA submission and

approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent term extension. An interim patent term extension increases the patent term by one year and may be renewed up to four times. For each interim patent term extension granted, the post-approval patent term extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug

covered by the patent for which a patent term extension is being sought is likely. Interim patent term extensions are not available for a drug for which an NDA has not been submitted.

Section 505(b)(2) new drug applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA s previous approval of a similar product, or published literature, in support of its application. We expect that the NDA for MM-398 will be submitted and reviewed under Section 505(b)(2).

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on the FDA s previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Combination products

A combination product is a product comprised of (i) two or more regulated components (i.e., drug/device, biologic/device, drug/biologic or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity; (ii) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (iii) a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where, upon approval of the proposed product, the labeling of the approved product would need to be changed (e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose); or (iv) any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

The FDA is divided into various branches, or Centers, by product type. Different Centers typically review drug, biologic or device applications. In order to review an application for a combination product, the FDA must decide which Center should be responsible for the review. FDA regulations require that the FDA determine the combination product s primary mode of action, or PMOA, which is the single mode of a combination product that provides the most

important therapeutic action of the combination product. The Center that regulates that portion of the product that generates the PMOA or that has expertise in the relevant therapeutic area becomes the lead evaluator. If there are two independent modes of action, neither of which is subordinate to the other, the FDA makes a determination as to which Center to assign the product based on consistency with other

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combination products raising similar types of safety and effectiveness questions or to the Center with the most expertise in evaluating the most significant safety and effectiveness questions raised by the combination product. When evaluating an application, a lead Center may consult other Centers but still retain complete reviewing authority, or it may collaborate with another Center, by which the lead Center assigns review of a specific section of the application to another Center, delegating its review authority for that section. Typically, the FDA requires a single marketing application submitted to the Center selected to be the lead evaluator, although the agency has the discretion to require separate applications to more than one Center. One reason to submit multiple evaluations is if the applicant wishes to receive some benefit that accrues only from approval under a particular type of application, like new drug product exclusivity. If multiple applications are submitted, each application may be evaluated by a different lead Center.

Biosimilars law

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, amended the PHSA to create a new licensure framework for biosimilar products, which could ultimately subject our biological products to competition. Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is biosimilar to or interchangeable with a referenced, branded biologic product. Previously, there had been no licensure pathway for such biosimilar or interchangeable products. For purposes of the BPCIA, a reference product is defined as the single biological product licensed under a full BLA against which a biological product is evaluated in an application submitted under a follow-on BLA. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the Secretary of the U.S. Department of Health & Human Services. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

The BPCIA also created a 12-year period of reference product exclusivity, which can be extended to 12 ½ years with pediatric exclusivity. The 12-year exclusivity period begins on the date of first licensure of the reference product under the PHSA and during which the licensure of a follow-on application for a biosimilar or interchangeable product cannot be made effective. During the first four years (or four and one-half years with pediatric exclusivity) of the 12-year period, an application for a biosimilar or interchangeable version of the reference product cannot be submitted to the FDA.

The BPCIA includes limits on obtaining 12-year reference product exclusivity for certain changes or modifications to the reference product. A separate 12-year reference product exclusivity period does not apply to:

a BLA supplement for the product that is the reference product;

a subsequent BLA filed by the same reference product sponsor or manufacturer (or a licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or

a modification to the structure of the biological product that does not result in a change in safety, purity or potency.

The FDA has not yet issued proposed regulations setting forth its interpretation of the BPCIA s provisions but has issued guidance documents related to BPCIA implementation.

In addition to creating a 12-year period of reference product exclusivity, the BPCIA clarifies the interaction of that exclusivity with orphan drug exclusivity, such that the licensure of a biosimilar or interchangeable version

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of a reference product that was designated and approved as an orphan drug may only occur after the later of the expiration of any applicable seven-year orphan drug exclusivity or the 12-year reference product exclusivity (or seven and one-half years and 12 ½ years with pediatric exclusivity).

Like pediatric exclusivity applicable to drug products approved under the FDCA, pediatric exclusivity applicable to biological reference products is subject to an exception. Pediatric exclusivity will not apply to either the 12-year reference product or the seven-year orphan drug exclusivity periods if the FDA determines later than nine months prior to the expiration of such period that the study reports a BLA sponsor submitted in response to a written request for pediatric studies met the terms of that request.

Our investigational biological products, if approved, could be considered reference products entitled to 12-year exclusivity. Even if our products are considered to be reference products eligible for exclusivity, another company could market a competing version of any of our biological products if the FDA approves a full BLA for such product containing the sponsor s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

The BPCIA also sets forth a complex mechanism for resolving patent disputes that involves a step-wise exchange of information prior to the initiation of a patent infringement lawsuit against a biosimilar or interchangeable product sponsor. Unlike the Hatch-Waxman Act, the BPCIA provides no automatic stay on approval of a biosimilar or interchangeable product application.

Overview of FDA regulation of companion diagnostics

We are developing *in vitro* and *in vivo* companion diagnostics for use in selecting the patients that we believe will respond to our cancer therapeutics.

The FDA published final guidance in July 2014 that addresses issues critical to developing *in vitro* companion diagnostics. The guidance provides that *in vitro* companion diagnostics that are essential for the safe and effective use of a corresponding therapeutic product must be approved contemporaneously with that therapeutic in most circumstances. Based on the guidance and the FDA s past treatment of companion diagnostics, we believe that the FDA will likely require one or more of our *in vitro* companion diagnostics to obtain PMA in conjunction with approval of the associated therapeutic, which will involve coordination of review by CDER and by the FDA s Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health.

Our *in vivo* companion diagnostics, which are in the form of imaging agents, are regulated as drugs by CDER and, as such, are generally subject to the regulatory requirements applicable to other new drug candidates.

PMA pathway

A medical device, including an *in vitro* diagnostic, or IVD, to be commercially distributed in the United States must receive either 510(k) clearance or PMA (or be a Class I exempt device that does not require pre-market review) from the FDA prior to marketing. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a preamendment class III device for which PMA applications have not been called, are placed in Class III requiring PMA. The PMA pathway requires proof of the safety and effectiveness of the device to the FDA s satisfaction. The PMA pathway generally takes from one to three years or even longer from submission of the application.

A PMA application for an IVD must provide extensive preclinical and clinical trial data. Preclinical data for an IVD includes many different tests, including how reproducible the results are when the same sample is tested multiple times by multiple users at multiple laboratories. The clinical data need to establish that the test is sufficiently safe, effective and reliable in the intended use population. In addition, the FDA must be convinced

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that a device has clinical utility, meaning that an IVD provides information that is clinically meaningful. A biomarker s clinical significance may be obvious, or the applicant may be able to rely upon published literature or submit data to show clinical utility.

A PMA application also must provide information about the device and its components regarding, among other things, device design, manufacturing and labeling. The sponsor must pay an application fee.

As part of the PMA review, the FDA will typically inspect the manufacturer s facilities for compliance with Quality System Regulation, or QSR, requirements, which impose elaborate design control, testing, control, documentation and other quality assurance procedures.

Upon submission, the FDA determines if the PMA application is sufficiently complete to permit a substantive review, and, if so, the FDA accepts the application for filing. The FDA then commences an in-depth review of the PMA application. The entire process typically takes one to three years, but may take longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided. The FDA also may respond with a not approvable determination based on deficiencies in the application and require additional clinical trials that are often expensive and time-consuming and can substantially delay approval.

During the review period, an FDA advisory committee, typically a panel of clinicians, likely will be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel s recommendation is important to the FDA s overall decision making process.

If the FDA s evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant s agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval.

Even after approval of a PMA, a new PMA or PMA supplement may be required in the event of a modification to the device, its labeling or its manufacturing process. Supplements to a PMA often require the submission of the same type of information required for an original PMA, except that the supplement is generally limited to the information needed to support the proposed change from the product covered by the original PMA.

Clinical trials

A clinical trial is almost always required to support a PMA application.

All clinical studies of investigational devices must be conducted in compliance with the FDA s requirements. If an investigational device could pose a significant risk to patients pursuant to FDA regulations, the FDA must approve an Investigational Device Exemption, or IDE, application prior to initiation of investigational use. IVD trials usually do not require an IDE, as the FDA does not judge them to be a significant risk because the results do not affect the patients in the study. However, for a trial where the IVD result directs the therapeutic care of patients with cancer (companion diagnostics), we believe that the FDA would consider the investigation to present significant risk and require an IDE.

An IDE application must be supported by appropriate data, such as laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The FDA typically grants

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IDE approval for a specified number of patients. A nonsignificant risk device does not require FDA approval of an IDE. Both significant risk and nonsignificant risk investigational devices require approval from IRBs at the study centers where the device will be used.

During the trial, the sponsor must comply with the FDA s IDE requirements for investigator selection, trial monitoring, reporting and record keeping. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and record keeping requirements. Prior to granting PMA, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with applicable requirements.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Post-market

After a device is on the market, numerous regulatory requirements apply. These requirements include: the QSR, labeling regulations, the FDA s general prohibition against promoting products for unapproved or off label uses, the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur, and the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA.

The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines, injunctions and civil penalties; recall or seizure of products; operating restrictions, partial suspension or total shutdown of production; refusing requests for PMA of new products; withdrawing PMAs already granted; and criminal prosecution.

Other regulatory requirements

Any drug or biological products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product s safety and effectiveness after commercialization. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to determine the overall survival benefit of the drug or biologic.

In addition, drug and biologic manufacturers and other entities involved in the manufacture and distribution of approved drugs and biological products are required to register their establishments with the FDA and state agencies,

and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA was also granted new inspection authorities under FDASIA. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and

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impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a Risk Evaluation and Mitigation Strategy program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled and warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- consent decrees, injunctions or the imposition of civil or criminal prosecution.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Additional provisions

Anti-kickback and false claims laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. The Patient Protection and Affordable Care Act, or the PPACA, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and

formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to

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customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the PPACA amended the federal false claims law such that a violation of the federal healthcare program anti-kickback statute can serve as a basis for liability under the federal false claims law. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Physician drug samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

Government price reporting

We will be required to report certain price data and pay certain rebates to the U.S. government as a condition of participation in federal healthcare programs. Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, we will be required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. For most brand name drugs, the amount of the basic rebate for each product is set by law as the greater of 23.1% (17.1% for clotting factors and certain other products) of the average manufacturer price, or AMP, or the difference between AMP and the best price available from us to any customer (with limited exceptions). The rebate amount must be adjusted upward if AMP increases more than inflation (measured by the Consumer Price Index Urban). This adjustment can cause the total rebate amount to exceed the minimum 23.1% (or 17.1%) basic rebate amount. The rebate amount is calculated each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare & Medicaid Services, or CMS. The requirements for calculating AMP and best price are complex. We are required to report any revisions to AMP or best price previously reported within a certain period, which revisions could affect our rebate liability for prior quarters. In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the statute governing the Medicaid Drug Rebate Program provides for civil monetary penalties.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part B generally covers drugs that must be administered by physicians or other healthcare practitioners, are provided in connection with certain durable medical equipment, or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. Medicare Part B pays for such drugs under a payment methodology based on the average sales price, or ASP, of the drugs. Manufacturers, including us, are required to provide ASP information to CMS on a quarterly basis. The manufacturer-submitted information is used to calculate Medicare payment rates. The payment rates for drugs in the hospital outpatient setting are subject to periodic adjustment. CMS also has the statutory authority to adjust payment rates for specific drugs outside the hospital outpatient setting based on a comparison of ASP payment rates to widely available market prices or to AMP, which could decrease Medicare payment rates, but the authority has not yet been implemented. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the governing statute provides for civil monetary penalties.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that do not need to be injected or otherwise administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for

prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The

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prescription drug plans negotiate pricing with manufacturers and may condition formulary placement on the availability of manufacturer discounts. Manufacturers, including us, are required to provide a 50% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

Our products will be subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule, or FSS. FSS participation is required for our products to be covered and reimbursed by the Veterans Administration, Department of Defense, Coast Guard and Public Health Service, or PHS. Coverage under Medicaid, the Medicare Part B program and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing equal to 76% of the non-federal average manufacturer price, or non-FAMP. An additional discount applies if non-FAMP increases more than inflation (measured by the Consumer Price Index Urban). In addition, if we fail to provide information timely or we are found to have knowingly submitted false information to the government, the governing statute provides for civil monetary penalties in addition to other penalties available to the government.

To maintain coverage of our products under the Medicaid Drug Rebate Program and Medicare Part B, we are required to extend discounts to certain covered entities that purchase products under the PHS pharmaceutical pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics, hemophilia treatment centers and other entities that receive health services grants from the PHS.

Foreign regulation

In order to market any therapeutic or diagnostic product outside of the United States, we need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

To date, other than applying for and being granted orphan medicinal product designation and obtaining advice from the Scientific Advice Working Party of the EMA in the European Union for MM-398 for the treatment of pancreatic cancer, we have not initiated any discussions with the EMA or any other foreign regulatory authorities with respect to seeking regulatory approval for any of our products in Europe or in any other country outside the United States.

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. In addition, orphan medicinal product designation can be granted if the drug is intended for a life threatening, seriously debilitating or serious and chronic condition and without incentives it is unlikely that sales of the drug in the European Union would be sufficient to justify developing the drug. Orphan medicinal product designation is only available if there is no other satisfactory method approved in the European

Union of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan medicinal product will be of significant benefit to patients. Orphan medicinal product designation

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provides opportunities for free protocol assistance and fee reductions for access to the centralized regulatory procedures. Orphan medicinal product designation also provides ten years of market exclusivity following drug approval. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Foreign Corrupt Practices Act

Various federal and foreign laws govern our international business practices with respect to payments to government officials. Those laws include the U.S. Foreign Corrupt Practices Act, or FCPA, which 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. In many countries, the healthcare professionals we may interact with may meet the FCPA s definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

We are subject also to the U.K. Bribery Act 2010, or Bribery Act, which 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. U.S. companies that conduct business in the United Kingdom generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances. Other countries have enacted similar anti-corruption laws and/or regulations.

New legislation and regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA.

In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations changed or what the effect of such changes, if any, may be.

For example, the BPCIA and the FDASIA were enacted in 2010 and 2012, respectively. The FDASIA is a broad, sweeping law that establishes new user fee programs and provides the FDA with new authority in the areas of drugs, biologics and medical devices. In particular, 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 also provides the FDA with additional authority to exercise against manufacturers of drugs or biologics that are not adhering to pediatric study requirements, which apply even if the manufacturer is not seeking to market the drug or biologic to pediatric patients.

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Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. Sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug candidates that we are developing and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing

emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the PPACA was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs

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sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies share of sales to federal healthcare programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As of January 31, 2015, we had 306 full-time employees, including a total of 85 employees with M.D. or Ph.D. degrees. Of these full-time employees, 240 employees are engaged in research, development and manufacturing. None of our employees is represented by a labor union or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our Corporate Information

We were originally incorporated in the Commonwealth of Massachusetts in 1993 and reincorporated under the laws of the State of Delaware in October 2010. Our principal executive offices are located at One Kendall Square, Suite B7201, Cambridge, MA 02139, and our telephone number is (617) 441-1000.

Information Available on the Internet

We maintain a website with the address *www.merrimackpharma.com*. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the SEC Filings section of our website as soon as reasonably practicable after those materials have been electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC. We also make available on our website our corporate governance guidelines, the charters for our audit committee, corporate governance and nominating committee, organization and compensation committee and executive committee, and our code of business conduct and ethics, which applies to our directors, officers and employees, and such information is available in print and free of charge to any of our stockholders who requests it. In addition, we intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be publicly disclosed pursuant to rules of the SEC.

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Item 1A. Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

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

Since inception, we have incurred significant operating losses. Our net loss was $83.6 million for the year ended December 31, 2014, $130.7 million for the year ended December 31, 2013 and $91.8 million for the year ended December 31, 2012. As of December 31, 2014, we had an accumulated deficit of $655.2 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities and a secured debt financing. We have devoted substantially all of our efforts to research and development, including clinical trials. We have not completed development of or commercialized any therapeutic product candidates or companion diagnostics. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

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

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

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

We currently have, and will continue to have, a significant amount of indebtedness. As of December 31, 2014, we had outstanding borrowings in an aggregate principal amount of $40.0 million under a Loan and Security Agreement, or Loan Agreement, with Hercules Technology Growth Capital, Inc., or Hercules. In addition, on July 17, 2013, we issued $125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020. We could in the future incur additional indebtedness beyond such amounts.

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

- requiring us to dedicate a substantial portion of cash flow from operations to the payment of interest on, and principal of, our debt, which will reduce the amounts available to fund working capital, capital expenditures, product development efforts and other general corporate purposes;

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- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- obligating us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

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

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

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

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

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

We will need substantial additional funding in connection with our continuing operations. We expect our research and development expenses to continue to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. In addition,

in connection with seeking and possibly obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts.

We expect to be able to fund operations into 2016 through our unrestricted cash and cash equivalents and available-for-sale securities of $124.0 million as of December 31, 2014, $66.5 million of net milestones related to

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MM-398 that we anticipate receiving from Baxter in 2015, after offsetting payments to PharmaEngine, and anticipated cost sharing reimbursements from Baxter. Our future capital requirements will depend on many factors, including:

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

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

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

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and these covenants may also require us to attain certain levels of financial performance and we may not be able to do so;

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any such failure may result in the acceleration of such debt and the foreclosure by our creditors on the collateral we used to secure the debt. The debt issued in a debt financing would also be senior to our outstanding shares of capital stock, and may rank equally with or senior to the convertible senior notes upon our liquidation. Our existing indebtedness and the pledge of our assets as collateral limit our ability to obtain additional debt financing. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

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

Risks Related to the Development and Commercialization of Our Product Candidates

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

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

- successful enrollment in, and completion of, preclinical studies and clinical trials;

- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States for our product candidates, including our companion diagnostics;

establishing commercial manufacturing capabilities, either by building such facilities ourselves or making arrangements with third-party manufacturers;

launching commercial sales of any approved products, whether alone or in collaboration with others;

acceptance of any approved products by patients, the medical community and third-party payors;

effectively competing with other therapies;

a continued acceptable safety profile of any products following approval; and

qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

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

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

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

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

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

- the supply or quality of our product candidates, companion diagnostics or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

For example, in February 2015, we stopped enrolling patients in our Phase 2 clinical trial of MM-111 for the treatment of advanced gastric, esophageal and gastroesophageal junction cancers prior to full enrollment based on a recommendation from the DSMB for the clinical trial, which cited shorter PFS 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

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in patients with ovarian cancer or in patients with breast cancer, although our ongoing biomarker analysis in each trial identified a potential subpopulation of patients benefiting from MM-121 in combination with either paclitaxel or exemestane, respectively.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We 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 Baxter and PharmaEngine will market and sell MM-398 in the rest of the world. Our commercialization plans for our other therapeutic candidates will depend in part on any future collaborations into which we may enter.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, 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 sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a 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.

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

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

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

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

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

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

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

Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such

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

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

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

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

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

substantial monetary awards to patients;

loss of revenue; and

the inability to commercialize any products that we may develop.

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

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

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

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

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

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

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

We plan to apply our Network Biology approach to multiple additional disease areas outside the oncology field. We expect to do so in some cases through the establishment of separately funded companies. For example, we established Silver Creek to 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

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contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

Under our license and collaboration agreement, Baxter has significant control over the conduct and timing of development and commercialization efforts with respect to MM-398 outside of the United States. We have little control over the amount, timing and quality of resources that Baxter devotes to the development or commercialization of MM-398 outside of the United States. If Baxter fails to devote sufficient financial and other resources to the future development or commercialization of MM-398 outside of the United States, 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 Baxter as a collaborator in the development or commercialization of MM-398, our business will be materially harmed.

Baxter has the right to terminate our agreement for the development and commercialization of MM-398, in whole or with respect to specified territories, at any time and for any reason, upon 180 days prior written notice.

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Baxter also has the right to terminate our agreement if we fail to cure a material breach of our agreement within a specified cure period, or fail to diligently pursue a cure if such a breach is not curable within such period.

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

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

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

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

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

Collaborations involving our product candidates, including our collaboration with Baxter, 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;

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collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

disputes may arise between us and the collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and

collaborations may be terminated, such as the termination of our license and collaboration agreement with Sanofi effective December 17, 2014, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

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

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

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

We do not independently conduct clinical trials of our product candidates. We rely on third parties, such as contract research organizations, clinical data management organizations, medical institutions and clinical investigators, to perform this function. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory agencies require us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that adverse event data are reported within required timeframes, that data and reported results are credible and accurate and that the

rights, integrity and confidentiality of patients in clinical trials are protected. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

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

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

Risks Related to the Manufacturing of Our Product Candidates

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

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

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

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

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

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

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

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

We currently rely on third-party manufacturers for some aspects of the production of our product candidates for preclinical testing and clinical trials, including 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.

Third-party manufacturers may not be able to comply with cGMP, 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.

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

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

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

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is

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expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors patent rights are highly uncertain. Our and our licensors pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Under the America Invents Act enacted in 2011, the United States moved to this first to file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. We may become involved in opposition, interference or derivation proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

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

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

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

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

We are currently engaged in an opposition proceeding in the European Patent Office to narrow or invalidate the claims of a European patent owned by a third party. For more information, see Part I, Item 3. Legal Proceedings of this Annual Report on Form 10-K. We have obtained a favorable interim decision in this opposition, although that decision is now under appeal. The ultimate outcome of this opposition remains uncertain. If we are not ultimately successful in this proceeding and the issued claims of the patent we are opposing are determined to be valid and construed to cover MM-111, we may not be able to commercialize MM-111 in some or all European countries without infringing such patents. If we infringe a valid claim of this patent, we would need to obtain a license to the patented technology, which may cause us to incur licensing-related costs. However, a license to the patent that is the subject of the opposition proceeding may not be available on commercially reasonable terms or at all. As a result, we could be liable for monetary damages or we may be forced to delay, suspend, forego or cease commercializing MM-111 in some or all countries in Europe if we were found to infringe a valid claim of the patent. In addition, even if we are ultimately successful in this opposition proceeding, such result would be limited to our activities in Europe.

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

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

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

In addition to our patented technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. In addition, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Regulatory Approval of Our Product Candidates

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

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

Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

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

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

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

In July 2014, the FDA issued final guidance that stated that if safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will not approve the therapeutic unless the FDA approves or clears this *in vitro* companion diagnostic device at the same time that the FDA approves the therapeutic. The approval or clearance of the *in vitro* diagnostic most likely will occur through the FDA s Center for Devices and Radiological Health Office of In Vitro Diagnostics and Radiological Health. Even with the issuance of the final guidance, the FDA s expectations for *in vitro* companion diagnostics remain unclear in some respects. The FDA s developing expectations will affect our *in vitro* companion diagnostics. In particular, the FDA may limit our ability to use retrospective data, otherwise disagree with our approaches to trial design, biomarker qualification, clinical and analytical validity and clinical utility, or make us repeat aspects of the trial or initiate new trials.

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

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

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

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

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

We have obtained orphan drug designation in the United States and orphan medicinal product designation in the European Union for MM-398 for the treatment of pancreatic cancer. In addition, we have obtained orphan drug designation in the United States for MM-111 for the treatment of esophageal, gastric and gastroesophageal junction cancers and for MM-141 for the treatment of pancreatic cancer. In the United States, under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

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

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

The 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 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

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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 BLA. The BPCIA is complex and is only beginning to be interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning is subject to uncertainty. While it is uncertain when any such processes may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

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

- a potential competitor could seek and obtain approval of its own BLA during our exclusivity period instead of seeking approval of a biosimilar version; and

- the FDA could consider a particular product candidate, such as MM-302, which contains both drug and biological product components, to be a drug subject to review pursuant to an NDA, and therefore eligible for a significantly shorter marketing exclusivity period as provided under the Drug Price Competition and Patent Term Restoration Act of 1984.

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

In addition, a drug product approved under an NDA, such as MM-398 if it were to be approved, could face generic competition earlier than expected. The enactment of the Generic Drug User Fee Amendments of 2012 as part of the 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 may be eligible for 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 and may be eligible for priority review status, 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 partners, both within and outside the United States. This may increase the risks described below with respect to our compliance with foreign regulations.

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

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

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the marketing of a product;
- restrictions on product distribution;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;

refusal to approve pending applications or supplements to approved applications that we submit;

recall of products;

fines, restitution or disgorgement of profits or revenue;

suspension or withdrawal of regulatory approvals;

refusal to permit the import or export of our products;

product seizure; or

injunctions or the imposition of civil or criminal penalties.

The FDASIA provides the FDA with new inspection authorities. A drug or biologic will be considered adulterated, with possible resulting civil and criminal penalties, if the owner or operator of the establishment where it is made, processed, packed or held delays, denies, limits or refuses inspection. The FDASIA also

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replaces the biennial inspection schedule for drugs and biologics with a risk-based inspection schedule. The law grants the FDA authority to require a drug or biologics manufacturer to provide, in advance or instead of an inspection, and at the manufacturer s expense, any records or other information that the agency may otherwise inspect at the facility. The FDASIA also permits the FDA to share inspection information with foreign governments under certain circumstances. The FDASIA is complex and has yet to be fully interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

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

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

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

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

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

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

reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors and

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customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

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

- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- the FCPA 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

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civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

Risks Related to Employee Matters and Managing Growth

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

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

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

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, manufacturing, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited

financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or

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recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

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

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

Risks Related to Our Common Stock

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

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

stockholders may desire.

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

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

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replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions:

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

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

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

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

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

- the success of competitive products or technologies;

results of clinical trials of our product candidates or those of our competitors;

regulatory or legal developments in the United States and other countries;

developments or disputes concerning patents or other proprietary rights;

the recruitment or departure of key personnel;

variations in our financial results or those of companies that are perceived to be similar to us;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts reports or recommendations;

general economic, industry and market conditions; and

the other factors described in this Risk Factors section.

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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 outstanding convertible notes, could cause the market price of our common stock to drop significantly, even if our business is doing well.

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal facilities consist of approximately 153,000 square feet of research, manufacturing and office space located at One Kendall Square in Cambridge, Massachusetts, including 31,620 square feet of research, manufacturing and office space pursuant to the amendment to our lease agreement that we entered into on February 23, 2015. For more information on this amendment, see Part II, Item 9B. Other Information Amendment to Facility Lease of this Annual Report on Form 10-K. The lease on all this space expires in June 2019. We retain an option to renew the lease on all of our current space for an additional period of either one or five years. In addition, on February 24, 2015, we exercised our right of first offer under the lease with respect to approximately 14,160 additional square feet in our Cambridge, Massachusetts facility. We expect to occupy this additional space in 2015 after negotiating and entering into an amendment to the lease for this additional space. We expect that the lease for this additional space will expire co-terminous with the existing lease in June 2019.

The facilities of our Silver Creek subsidiary consist of approximately 1,878 square feet of research and office space located in San Francisco, California. The lease on this space is month-to-month.

Item 3. Legal Proceedings

We are currently engaged in an opposition proceeding in the European Patent Office to narrow or invalidate the claims of a European patent owned by a third party. In September 2008, we filed a notice of opposition to a patent (EP 1187634) held by Zensun (Shanghai) Science and Technology Ltd., or Zensun, on the grounds of

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added matter, insufficient disclosure, lack of novelty and lack of inventive step. If the issued claims of the Zensun patent were determined to be valid and construed to cover MM-111, our development and commercialization of MM-111 in Europe could be delayed or prevented. In August 2010, the European Patent Office issued a written decision revoking Zensun s patent. Zensun has appealed this decision. Pending the outcome of this appeal, the original issued claims of the Zensun patent remain in effect. Each party has submitted written statements regarding the appeal to the European Patent Office. Oral proceedings for the appeal are scheduled for March 2015. Although we have obtained a favorable interim decision in this opposition, that decision is now under appeal and the ultimate outcome of this opposition remains uncertain.

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

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is publicly traded on the NASDAQ Global Market under the symbol MACK . The following table sets forth, for the quarterly periods indicated, the high and low sales prices of our common stock as reported on the NASDAQ Global Market for each quarter in the years ended December 31, 2013 and 2014.

	High	Low
Year ended December 31, 2013		
First quarter	$ 6.69	$ 5.90
Second Quarter	$ 6.76	$ 4.06
Third Quarter	$ 7.09	$ 3.26
Fourth Quarter	$ 5.41	$ 2.05
Year ended December 31, 2014		
First Quarter	$ 6.46	$ 4.51
Second Quarter	$ 8.25	$ 4.13
Third Quarter	$ 8.99	$ 5.53
Fourth Quarter	$ 11.47	$ 7.36

Holders

As of January 31, 2015, there were approximately 182 holders of record of our common stock. This number does not include beneficial owners whose shares are held by nominees in street name.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future.

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Corporate Performance Graph

The following performance graph and related information shall not be deemed to be soliciting material or to be filed with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the NASDAQ Composite Index and to the NASDAQ Biotechnology Index from March 29, 2012 (the first date that shares of our common stock were publicly traded) through December 31, 2014. The comparison assumes $100 was invested after the market closed on March 29, 2012 in our common stock and in each of the foregoing indices, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

COMPARISON CUMULATIVE TOTAL RETURN

Among the NASDAQ Composite Index, the NASDAQ Biotechnology Index and Merrimack Pharmaceuticals, Inc.

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Item 6. Selected Financial Data

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K and the Management s Discussion and Analysis of Financial Condition and Results of Operations section of this Annual Report on Form 10-K. We have derived the consolidated statements of comprehensive loss data for the years ended December 31, 2014, 2013 and 2012 and the consolidated balance sheet data as of December 31, 2014 and 2013 from our audited consolidated financial statements included in this Annual Report on Form 10-K. We have derived the consolidated statements of comprehensive loss data for the years ended December 31, 2011 and 2010 and the consolidated balance sheet data as of December 31, 2012, 2011 and 2010 from our audited consolidated financial statements not included in this Annual Report on Form 10-K. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

	Years ended December 31,				
(in thousands, except per share amounts)	**2014 (1)**	**2013 (1)**	**2012 (1)**	**2011 (1)**	**2010 (1)**
Consolidated statements of comprehensive loss data					
Collaboration revenues	$ 102,756	$ 47,786	$ 48,921	$ 34,215	$ 20,305
Operating expenses:					
Research and development	138,495	147,139	125,858	100,630	58,278
General and administrative	30,517	21,187	15,805	14,454	11,381
Contingent consideration					(178)
Total operating expenses	169,012	168,326	141,663	115,084	69,481
Loss from operations	(66,256)	(120,540)	(92,742)	(80,869)	(49,176)
Other income and expenses:					
Interest income	114	166	184	56	74
Interest expense (2)	(18,230)	(10,938)	(553)	(13)	(3,726)
Other, net	813	627	1,357	1,150	2,669
Net loss before income taxes	(83,559)	(130,685)	(91,754)	(79,676)	(50,159)
Benefit from income taxes					
Net loss	(83,559)	(130,685)	(91,754)	(79,676)	(50,159)
Less net income (loss) attributable to non-controlling interest	(268)	240	(477)	(453)	(55)
Net loss attributable to Merrimack Pharmaceuticals, Inc.	(83,291)	(130,925)	(91,277)	(79,223)	(50,104)
Net loss per share available to common stockholders basic and diluted (3)	($ 0.80)	$ (1.32)	$ (1.28)	$ (7.67)	$ (5.57)
Weighted-average common shares used in computing net loss per share available to common stockholders basic and diluted (4)	104,410	98,919	72,831	11,343	10,994

(1) In August 2010, and thereafter, we acquired a controlling interest in and consolidated Silver Creek.

(2) In July 2013, we issued $125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020 in an underwritten public offering. In November and December 2012, we borrowed an aggregate principal amount of $40.0 million under our Loan Agreement with Hercules. In October 2010, we reissued Series F convertible preferred stock, or Series F preferred stock, and recorded Series F preferred stock proceeds received in advance of the reissuance as a short-term liability and recognized noncash imputed interest expense for financial statement purposes for the years ended December 31, 2010. Upon completion of the reissuance of Series F preferred stock in October 2010, the Series F preferred stock liability was relieved and we recorded the investment as convertible preferred stock and the accrued noncash interest expense as additional paid-in capital.

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(3) The numerator in the calculation of net loss per share available to common stockholders basic and diluted includes unaccreted dividends on our convertible preferred stock.

(4) In April 2012, we closed our initial public offering, which resulted in the sale of approximately 15.0 million shares of common stock and the conversion of all shares of outstanding convertible preferred stock into approximately 66.3 million shares of common stock. In July 2013, we closed an underwritten public offering of common stock, which resulted in the sale of approximately 5.75 million shares of common stock.

	As of December 31,				
(in thousands)	**2014**	**2013**	**2012 (1)**	**2011**	**2010**
Consolidated balance sheet data					
Cash and cash equivalents (2)	$ 35,688	$ 65,086	$ 37,714	$ 50,454	$ 30,713
Available-for-sale securities (2)	88,340	90,116	72,238		
Total assets	158,656	192,417	148,974	85,299	57,577
Loans payable	39,557	39,097	39,855		
Capital lease obligations				48	491
Derivative liability			196		
4.50% convertible senior notes (2)	80,595	72,578			
Deferred revenues	94,957	75,475	80,464	85,745	73,782
Convertible preferred stock warrants				1,516	652
Total liabilities	260,727	235,545	155,394	106,990	85,257
Non-controlling interest	69	337	97	574	1,027
Convertible preferred stock				268,225	191,257
Total stockholders deficit	(102,140)	(43,465)	(6,517)	(290,490)	(219,964)

(1) Upon closing of our initial public offering in April 2012, all outstanding shares of our convertible preferred stock were converted into 66.3 million shares of common stock, all outstanding warrants to purchase shares of convertible preferred stock were converted into warrants to purchase shares of common stock and approximately $4.3 million of cash dividends became payable to the holders of Series B convertible preferred stock.

(2) In July 2013, we sold an aggregate of 5.75 million shares of our common stock at a price to the public of $5.00 per share and issued $125.0 million aggregate principal amount of convertible senior notes in concurrent underwritten public offerings, in which we received aggregate net proceeds of approximately $147.3 million, after deducting underwriting discounts and commissions and offering expenses payable by us. $51.9 million net of issuance costs of the aggregate principal amount of the convertible senior notes is considered a conversion feature and is included as a component of stockholders deficit.

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth in Part I, Item 1A. Risk Factors of this Annual Report on Form 10-K, which are incorporated herein by reference, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines consisting of novel therapeutics paired with companion diagnostics for the treatment of cancer. We were founded by a team of scientists from The Massachusetts Institute of Technology and Harvard University who sought to develop a systems biology-based approach to biomedical research. The core of our approach to systems biology is to apply multidisciplinary and multitechnology capabilities to build functional and predictive computational models of biological systems, such as cell signaling networks, that allow us to engineer treatments that are directed at the mechanisms of disease. Our mission is to employ these insights to provide patients, physicians and the healthcare system with the medicines, tools and information to deliver integrated healthcare solutions that improve both the quality of outcomes and the efficiency of care. We currently have six targeted therapeutic oncology candidates in clinical development. Our most advanced program is our investigational agent MM-398. We have initiated a New Drug Application, or NDA, submission with the U.S. Food and Drug Administration, or FDA, for MM-398 as a treatment for metastatic pancreatic cancer in combination with 5-fluorouracil, or 5-FU, and leucovorin in patients who have been previously treated with gemcitabine. Additionally, we have multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines.

We have devoted substantially all of our resources to our drug discovery and development efforts, including advancing our systems biology approach, conducting clinical trials for our product candidates, protecting our intellectual property, preparing for commercial launch of MM-398 and providing general and administrative support for these operations. We have not generated any revenue from product sales and, to date, have financed our operations primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities and a secured debt financing. Through December 31, 2014, we have received $268.2 million from the sale of convertible preferred stock and warrants, $126.7 million of net proceeds from the sale of common stock during our April 2012 initial public offering and July 2013 follow-on underwritten public offering, $39.6 million of net proceeds from a secured debt financing, $120.6 million of net proceeds from the issuance of 4.50% convertible senior notes due 2020, or the convertible senior notes, in our July 2013 underwritten public offering and $342.2 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaborations. We have also entered into an arrangement to use our manufacturing capabilities to manufacture drug product on behalf of a third-party pharmaceutical company, for which we have received $3.8 million in upfront fees and reimbursements as of December 31, 2014. As of December 31, 2014, we had unrestricted cash and cash equivalents and available-for-sale securities of $124.0 million.

We expect to be able to fund operations into 2016 through our unrestricted cash and cash equivalents and available-for-sale securities of $124.0 million as of December 31, 2014, $66.5 million of net milestones related to MM-398 that we anticipate receiving from Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, which we collectively refer to as Baxter, in 2015, after offsetting payments to PharmaEngine, Inc., or PharmaEngine, and anticipated cost sharing reimbursements from Baxter.

We have never been profitable and, as of December 31, 2014, we had an accumulated deficit of $655.2 million. Our net loss was $83.6 million for the year ended December 31, 2014, $130.7 million for the year ended December 31, 2013 and $91.8 million for the year ended December 31, 2012. We expect to continue to

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incur significant expenses and increasing operating losses for at least the next several years. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical trials of our product candidates, including multiple simultaneous clinical trials for certain product candidates, some of which we expect will be entering late stage clinical development. In addition, in connection with seeking and possibly obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. We will need to generate significant revenues to achieve profitability, and we may never do so.

Strategic Partnerships, Licenses and Collaborations

Baxter

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

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

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

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

supports any challenge of our licensed patent rights.

Under the Baxter agreement, we granted Baxter a right of first negotiation to obtain a license to develop and commercialize MM-111, MM-141 and MM-302 outside of the United States. Baxter has also agreed that, subject

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to limited exceptions, until September 23, 2017, neither Baxter nor any of its affiliates will (i) effect or seek, offer or propose to effect, or cause or participate in or in any way advise, assist or encourage any other person to effect or seek, offer or propose to effect or cause or participate in, any acquisition of any of our securities or assets, any tender or exchange offer, merger or other business combination involving us, any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to us, or any solicitation of proxies or consents to vote any of our voting securities, (ii) form, join or in any way participate in a group with respect to any of our securities, (iii) otherwise act, alone or in concert with others, to seek to control or influence our management, board of directors or policies, (iv) take any action that might force us to make a public announcement regarding any of the foregoing or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing.

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

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

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

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

During the year ended December 31, 2014, we recognized $10.5 million of revenue associated with these payment amounts. As of December 31, 2014, there was $91.2 million of deferred revenue related to the Baxter agreement, $59.3 million of which is classified as current based upon our estimate of revenue that will be recognized as a result of effort expected to be completed within the next twelve months. As of December 31, 2014, we had $1.6 million of unbilled accounts receivable outstanding with Baxter.

Sanofi

In September 2009, we entered into a license and collaboration agreement with Sanofi, which we refer to as the Sanofi agreement, for the development and commercialization of MM-121. Through December 31, 2014, Sanofi has paid us a nonrefundable, noncreditable upfront license fee of $60.0 million and aggregate milestone payments of $25.0 million. Under the Sanofi agreement, Sanofi was also responsible for all MM-121 development and manufacturing costs. Sanofi reimbursed us for internal time at a designated full-time equivalent rate per year and for direct costs and services related to the development and manufacturing of MM-121.

On June 17, 2014, we agreed with Sanofi to terminate the Sanofi agreement effective December 17, 2014. In connection with the agreement to terminate the Sanofi agreement, among other things, Sanofi transferred

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ownership of the investigational new drug application for MM-121 back to us in July 2014, and we waived Sanofi s obligation to reimburse us for MM-121 development costs incurred after the effective termination date.

The timing of cash received from Sanofi differs from revenue recognized for financial statement purposes. We recognized revenue for development services within the period they are incurred and billable. Billable expenses were defined during each specified budget period. In the event that total development services expense incurred and expected to be incurred during any particular budget period exceeded the total contractually allowed billable amount for development services during the same period, we recognized only a percentage of the development services incurred as revenue in that period.

This percentage was calculated as total development services expense incurred during the specified period divided by the sum of total development services expense incurred plus estimated development services expense to be incurred during the specified period, multiplied by the total contractually allowed billable amount for development services during the specified period, less development services revenue recognized within the specified period. We recognized revenue on expenses incurred in excess of this percentage in the budget period when the excess amounts became contractually billable. We also recognized revenue for the upfront payment, milestone payments and manufacturing services using the contingency-adjusted performance model over the expected development period, which was initially estimated to be 12 years from the effective date of the Sanofi agreement. As a result of the agreement to terminate the Sanofi agreement, the development period was revised to end as of December 17, 2014. During the years ended December 31, 2014, 2013 and 2012, we recognized revenue based on the following components of the Sanofi agreement:

	Years ended December 31,		
(in thousands)	**2014**	**2013**	**2012**
Upfront payment	$ 39,306	$ 5,000	$ 5,000
Milestone payments	16,377	2,083	2,975
Development services	18,904	36,283	36,905
Manufacturing services and other	17,709	3,867	3,307
Total	$ 92,296	$ 47,233	$ 48,187

The increase in the revenue recognized during the year ended December 31, 2014 is due to the reduced development period under the Sanofi agreement, which terminated effective December 17, 2014. We do not expect to receive any further revenues under the Sanofi agreement.

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

Actavis

In November 2013, we entered into a development, license and supply agreement with Watson Laboratories, Inc., or Actavis, which we refer to as the Actavis agreement, pursuant to which we will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection, or the initial product, to Actavis. Under the Actavis agreement, Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the Actavis agreement, we have also agreed to develop additional products for Actavis in the future, the identities of which will be mutually agreed upon. We are eligible to receive up to $15.5 million, of which $3.8 million

has been received through December 31, 2014, and the remainder is expected to be received in development funding and development, regulatory and commercial milestone payments related to the initial product. We will also receive a double digit percentage of net profits on global sales of the initial product and any additional products. We will manufacture and supply the initial product to Actavis in bulk form at an agreed upon unit price. In January 2015, we amended the Actavis agreement to transfer certain responsibilities from us to Actavis in exchange for reducing the aggregate milestone payments that we are eligible to receive by $0.4 million.

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

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

Silver Creek Pharmaceuticals, Inc.

In 2010, we established Silver Creek Pharmaceuticals, Inc., or Silver Creek, as a subsidiary. Silver Creek s mission is to apply our Network Biology approach to the research and development of regenerative medicines to repair the heart. On December 31, 2014 and December 31, 2013, $1.0 million and $2.6 million, respectively, of convertible notes and related accrued interest converted to shares of Series A preferred stock of Silver Creek. As of December 31, 2014 and 2013, we owned approximately 60% and 64%, respectively, of the outstanding preferred stock of Silver Creek. We concluded that Silver Creek is a variable interest entity and that we are the primary beneficiary. We have the ability to direct the activities of Silver Creek through our ownership percentage and through the board of directors seats controlled by us and our de facto agents, and therefore, we consolidate Silver Creek for financial reporting purposes.

In the future, we may consider forming additional businesses or business units to apply our Network Biology approach to multiple additional disease areas outside the oncology field. We expect to do so in some cases, as with Silver Creek, through the establishment of separately funded companies.

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

In September 2005, Hermes BioSciences, Inc., or Hermes, which we acquired in October 2009, entered into a license agreement with PharmaEngine under which PharmaEngine received an exclusive license to research, develop, manufacture and commercialize MM-398 in Europe and certain countries in Asia. In May 2011, we entered into a new agreement with PharmaEngine under which we reacquired all previously licensed rights for MM-398, other than rights to commercialize MM-398 in Taiwan. As a result, we had the exclusive right to commercialize MM-398 in all territories in the world, except for Taiwan, where PharmaEngine has an exclusive commercialization right. Upon entering into the May 2011 agreement with PharmaEngine, we paid PharmaEngine a $10.0 million upfront license fee. In addition, we made a milestone payment of $5.0 million to PharmaEngine in connection with dosing the first patient in our Phase 3 clinical trial of MM-398, which occurred and was paid in the first quarter of 2012.

On September 22, 2014, we amended the PharmaEngine agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that we are required to pay to PharmaEngine. As a result of this amendment, we made a $7.0 million milestone payment to PharmaEngine. Additionally, as a result of this amendment, a previously contingent $5.0 million milestone payment is now payable to PharmaEngine upon the earlier of either the FDA s acceptance of an NDA for MM-398 or April 30, 2015. Prior to the amendment of the PharmaEngine agreement, this milestone payment was contingent upon the award of certain specified regulatory designations. These milestone payments were recognized as research and development expense during the year ended December 31, 2014.

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Since entering into the PharmaEngine agreement, we have paid PharmaEngine an aggregate of $22.0 million in upfront license fees and milestone payments, with an additional $5.0 million contractually obligated in 2015. In addition to these amounts, we will also be required to pay PharmaEngine up to an additional $70.0 million in aggregate regulatory milestones, including $11.0 million of expected milestones to be paid in 2015, and $130.0 million in aggregate sales milestones, in each case with respect to Europe and certain countries in Asia. PharmaEngine is also entitled to tiered royalties on net sales of MM-398 in Europe and certain countries in Asia. The royalty rates under the PharmaEngine agreement range from high single digits up to the low teens as a percentage of our net sales of MM-398 in these territories. Under the PharmaEngine agreement, we are responsible for all future development costs of MM-398 except those required specifically for regulatory approval in Taiwan. During the year ended December 31, 2014, 2013 and 2012, we recognized research and development expenses of $12.6 million, $1.5 million and $6.2 million, respectively, related to the PharmaEngine agreement, which included $12.0 million of expenses related to milestone payments in 2014 and a $5.0 million of expenses related to milestone payments in 2012. Our financial obligations under other license and development agreement are summarized below under Liquidity and Capital Resources Contractual obligations and commitments.

Financial Operations Overview

Revenues

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

We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, research, development and manufacturing efforts and reimbursements, milestone and other payments from collaborations, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. We do not expect to generate revenue from product sales until late 2015 at the earliest, if at all. If we or our collaborators fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected. We expect that revenues in 2015 under the Baxter agreement will exceed revenues in 2014, as we will have performed a full year of services under the Baxter agreement. The Sanofi agreement terminated effective December 17, 2014, and we do not expect to receive any further revenues under the agreement.

Research and development expense

Research and development expenses consist of the costs associated with our research and discovery activities, including investment in our Network Biology approach, conduct of preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings. Our research and development expenses consist of:

- employee salaries and related expenses, which include stock compensation and benefits for the personnel involved in our drug discovery and development activities;

external research and development expenses incurred under agreements with third-party contract research organizations and investigative sites;

manufacturing material expense for in-house manufacturing and third-party manufacturing organizations and consultants;

license fees for and milestone payments related to in-licensed products and technologies; and

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

We expense research and development costs as incurred. Conducting a significant amount of research and development is central to our business model. Product candidates in late stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late stage clinical trials. We plan to maintain or increase our research and development expenses for the foreseeable future as we continue development of our six most advanced product candidates, MM-398, MM-121, MM-111, MM-302, MM-151 and MM-141, and to further advance our preclinical products and earlier stage research and development projects.

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

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

	Years ended December 31,		
(in thousands)	**2014**	**2013**	**2012**
MM-398	$ 31,792	$ 28,135	$ 22,321
MM-302	13,982	7,906	7,126
MM-121	10,707	45,144	37,173
MM-111	14,437	16,251	14,249
MM-151	9,038	6,909	7,236
MM-141	14,611	6,758	8,963
Preclinical, general research and discovery	37,045	30,082	24,556
Stock compensation	6,883	5,954	4,234
Total research and development expense	$ 138,495	$ 147,139	$ 125,858

The development, regulatory and clinical expenses related to the agreement we entered into with Actavis in November 2013 are included within our preclinical, general research and discovery expenses for the years ended December 31, 2014 and 2013.

The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, other than as discussed below, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our preclinical or clinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;

the potential benefits of our product candidates over other therapies;

our ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;

future clinical trial results;

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- the terms and timing of regulatory approvals; and

- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of clinical development of a product candidate or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

MM-398

We have initiated an NDA submission with the FDA for MM-398 as a treatment for metastatic pancreatic cancer in combination with 5-FU and leucovorin in patients who have been previously treated with gemcitabine. We recently expanded a Phase 1 translational clinical study designed to identify predictive biomarkers associated with MM-398 for the purpose of estimating drug delivery to the tumor and patient response. In addition, we are also collaborating with several investigators to conduct additional trials of MM-398, including an investigator-sponsored Phase 2 clinical trial in colorectal cancer, an investigator-sponsored Phase 1 clinical trial in glioma and an investigator-initiated Phase 1 clinical trial in pediatric solid tumors, which is being conducted under our investigational new drug application.

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

MM-302

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

MM-121

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

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MM-111

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

MM-151

We are currently conducting one Phase 1 clinical trial of MM-151 in solid tumors. During the first quarter of 2012, we made a $1.5 million payment under our collaboration agreement with Adimab LLC, or Adimab.

MM-141

We are currently conducting one Phase 1 clinical trial of MM-141 in solid tumors. We anticipate initiating a Phase 2 clinical trial of MM-141 in front-line pancreatic cancer in 2015.

General and administrative expense

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

Interest expense

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

Other income

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

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with the rules and regulations of the

Securities and Exchange Commission, or the SEC, and generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets

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and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Estimates include revenue recognition, lease accounting, valuation of derivative liabilities and embedded conversion options, useful lives with respect to long-lived assets and intangibles, valuation of stock options, convertible preferred stock warrants, contingencies, accrued expenses and other, intangible assets, goodwill, in-process research and development and tax valuation reserves. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

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

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Revenue recognition

We enter into biopharmaceutical product development agreements with collaborators for the research and development of therapeutic and diagnostic products. The terms of these agreements may include non-refundable signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. We assess these multiple elements in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification 605, *Revenue Recognition*, in order to determine whether particular components of the arrangement represent separate units of accounting.

In January 2011, we adopted authoritative guidance on revenue recognition for multiple element arrangements. This guidance, which applies to multiple element arrangements entered into or materially modified on or after January 1, 2011, separates and allocates consideration in a multiple element arrangement according to the relative selling price of each deliverable. The fair value of deliverables under the arrangement may be derived using a best estimate of selling price if vendor specific objective evidence and third-party evidence are not available.

Deliverables under the arrangement will be separate units of accounting provided that a delivered item has value to the customer on a stand-alone basis and if the arrangement does not include a general right of return relative to the delivered item and delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor.

We entered into the Baxter agreement in September 2014, which was evaluated under the accounting guidance on revenue recognition for multiple element arrangements. We determined that the obligations under this agreement represent a single unit of accounting and that the agreement represents a services agreement. As a result we have estimated the level of effort expected to be completed as a result of providing the identified deliverables and will recognize revenue related to the agreement based on proportional performance as effort is completed over the expected services period.

We entered into the Actavis agreement in November 2013, which was evaluated under the accounting guidance on revenue recognition for multiple element arrangements. We determined that the obligations represent a single unit of accounting and will recognize revenue as product is supplied to Actavis. Therefore, we have deferred total billed and

billable milestones and development expenses related to this agreement. All

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milestone payments received and development expenses reimbursed until the period of commercialization will be deferred, and upon commercialization will be recognized over the delivery period of the bulk drug to Actavis.

Our other existing collaboration agreements continue to be accounted for under previously issued revenue recognition guidance for multiple element arrangements and milestone revenue recognition, as described below. We recognized upfront license payments as revenue upon delivery of the license only if the license had stand-alone value and the fair value of the undelivered performance obligations could be determined. If the fair value of the undelivered performance obligations could be determined, such obligations were accounted for separately as the obligations were fulfilled. If the license was considered to either not have stand-alone value or have stand-alone value but the fair value of any of the undelivered performance obligations could not be determined, the arrangement was accounted for as a single unit of accounting and the license payments and payments for performance obligations were recognized as revenue over the estimated period of when the performance obligations would be performed.

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

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

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

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

Marketable securities

Our holdings of marketable securities may consist of U.S. government agencies securities, commercial paper, corporate notes and bonds and certificates of deposit, which are maintained by an investment manager and have expected average maturity dates in excess of three months. We classify these investments as available-for-sale. Available-for-sale securities are carried at fair value, with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders deficit until realized. Realized gains and losses are recognized in interest income. Any premium or discount arising at purchase is amortized and/or accreted to interest income.

Goodwill

Goodwill represents the difference between the purchase price and the fair value of the tangible and identifiable intangible net assets acquired. Goodwill is not amortized but is evaluated for impairment within our single reporting unit on an annual basis, during the third quarter, or more frequently if an event occurs or

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circumstances change that would more likely than not reduce the fair value of our reporting unit below its carrying amount. When performing an evaluation of goodwill impairment, we have the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative two-step impairment test. If we elect this option and find, as a result of the qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, the quantitative two-step impairment test must be performed; otherwise, no further testing is required. This requires us to assess the impact of significant events, milestones and changes to expectations and activities that may have occurred since the last impairment evaluation. Significant changes to these estimates, judgments and assumptions could materially change the outcome of the impairment assessment. Alternatively, we may elect to not first assess qualitative factors and immediately perform the quantitative two-step impairment test. If such an election occurs, in the first step, the fair value of our reporting unit is compared to the carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting unit s goodwill. If the carrying value of the reporting unit s goodwill exceeds the implied fair value, then we would record an impairment loss equal to the difference.

Accrued expenses

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

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

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

Stock-based compensation

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based awards made to employees, including stock options, based on the estimated grant date fair values. For employees, we use the straight-line method to allocate compensation expense to reporting periods over each optionee s requisite service period, which is generally the vesting period. For non-employees, we record awards at fair value, periodically

remeasure awards to reflect the current fair value at each reporting period and recognize expense over the related service period. When applicable, we account for these equity instruments based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable.

We estimate the fair value of stock-based awards to employees and non-employees using the Black-Scholes option valuation model. Determining the fair value of stock-based awards requires the use of highly subjective assumptions, including volatility, the calculation of expected term, risk free interest rate and the fair value of the

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underlying common stock on the date of grant, among other inputs. The assumptions used in determining the fair value of stock-based awards represent our best estimates, which involve inherent uncertainties and the application of judgment. As a result, if factors change, and different assumptions are used, our level of stock-based compensation could be materially different in the future.

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

JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. Among other provisions, the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Prior to 2014, we had previously elected to delay such adoption of new or revised accounting standards. Because the market value of our common stock held by non-affiliates exceeded $700.0 million as of June 30, 2014, we ceased to be an emerging growth company as of December 31, 2014. However, as a result of relying on these exemptions for fiscal years ending prior to December 31, 2014, we may not comply with new or revised accounting standards for such years on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

Results of Operations

Comparison of the years ended December 31, 2014 and 2013

	Years ended December 31,	
(in thousands)	**2014**	**2013**
Collaboration revenues	$ 102,756	$ 47,786
Research and development expenses	(138,495)	(147,139)
General and administrative expenses	(30,517)	(21,187)
Loss from operations	(66,256)	(120,540)
Interest income	114	166
Interest expense	(18,230)	(10,938)
Other income	813	627
Net loss	$ (83,559)	$ (130,685)

Collaboration revenues

Collaboration revenues for 2014 were $102.8 million, compared to $47.8 million for 2013, an increase of $55.0 million, or 115%. The increase was primarily attributable to the reassessment of the development period of our collaboration with Sanofi based on the decision to terminate the arrangement effective December 17, 2014.

Additionally, revenues increased as a result of the recognition of $10.5 million of revenue related to our collaboration with Baxter.

Research and development expenses

Research and development expenses for 2014 were $138.5 million, compared to $147.1 million for 2013, a decrease of $8.6 million, or 6%. This decrease was primarily attributable to $34.4 million of decreased MM-121 spending primarily due to costs associated with analyzing and concluding ongoing and completed clinical trials.

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Additionally, there were $1.8 million of decreased MM-111 expenses associated with ongoing efforts related to our Phase 2 clinical trial. These decreases were partially offset by:

$7.9 million of increased MM-141 expenses primarily due to costs associated with a manufacturing campaign as well as ongoing clinical trials and diagnostic efforts;

$7.0 million of increased spending on preclinical, general research and discovery primarily due to an increased number of preclinical programs in our pipeline and increased costs associated with each preclinical program as these programs approach clinical development;

$6.1 million of increased MM-302 expenses primarily due to costs associated with our ongoing clinical trials as well as the timing of manufacturing campaigns;

$3.7 million of increased MM-398 expenses primarily due to $12.0 million of non-recurring milestone payment obligations incurred as a result of the amendment of the PharmaEngine agreement, partially offset by decreased costs associated with analyzing and concluding ongoing and completed clinical trials in metastatic pancreatic cancer;

$2.1 million of increased MM-151 expenses associated with a manufacturing campaign as well as ongoing clinical trials and diagnostic efforts; and

$0.9 million of increased stock compensation expense due the annual grant of stock options to employees;

General and administrative expenses

General and administrative expenses for 2014 were $30.5 million, compared to $21.2 million for 2013, an increase of $9.3 million, or 44%. This increase was primarily attributable to increases in labor and labor-related costs, efforts to prepare for potential commercialization of our product candidates and increased facility-related costs.

Interest expense

Interest expense for 2014 was $18.2 million, compared to $10.9 million for 2013. This increase was primarily attributable to a full year of interest expense being recorded related to the convertible senior notes issued in July 2013.

Other income

Other income for 2014 and 2013 was $0.8 million and $0.6 million, respectively, which was primarily related to the amortization of Massachusetts Life Sciences Center, or MLSC, tax incentives.

Results of Operations

Comparison of the years ended December 31, 2013 and 2012

(in thousands)	Years ended December 31, 2013	2012
Collaboration revenues	$ 47,786	$ 48,921
Research and development expenses	(147,139)	(125,858)
General and administrative expenses	(21,187)	(15,805)
Loss from operations	(120,540)	(92,742)
Interest income	166	184
Interest expense	(10,938)	(553)
Other income	627	1,357
Net loss	$ (130,685)	$ (91,754)

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Collaboration revenues

Collaboration revenues for 2013 were $47.8 million, compared to $48.9 million for 2012, a decrease of $1.1 million, or 2%. Increases in MM-121 research and development expenses were offset by decreases primarily attributable to recognizing revenue only up to the approved collaboration budget for 2013 pursuant to the Sanofi agreement.

Research and development expenses

Research and development expenses for 2013 were $147.1 million, compared to $125.9 million for 2012, an increase of $21.3 million, or 17%. This increase was primarily attributable to:

- $8.0 million of increased MM-121 spending primarily due to increased enrollment and clinical analysis and costs associated with our ongoing clinical trials and close-down costs associated with clinical trials that have reported results;
- $5.8 million of increased MM-398 spending primarily due to due to increased enrollment and costs associated primarily with our ongoing Phase 3 clinical trial of $10.8 million, partially offset by the absence of a $5.0 million milestone payment that occurred in the first quarter of 2012;
- $4.7 million of increased spending on preclinical, general research and discovery primarily due to an increased number of preclinical programs in our pipeline and increased costs associated with each preclinical program as these programs approach clinical development;
- $2.0 million of increased MM-111 spending due to the initiation and ongoing efforts related to our Phase 2 clinical trial;
- $1.7 million of increased stock compensation expense due the annual grant of stock options to employees;
- $0.8 million of impairment charge related to in-process research and development for an early-stage preclinical program; and
- $0.8 million of increased MM-302 spending due to increased enrollment and costs associated with ongoing clinical trials.

These costs were partially offset by $2.5 million of decreased spending on MM-151 and MM-141, primarily due to the timing of costs associated with ongoing clinical trials.

General and administrative expenses

General and administrative expenses for 2013 were $21.2 million, compared to $15.8 million for 2012, an increase of $5.4 million, or 34%. This increase was primarily attributable to increases in labor and labor-related costs, efforts to

prepare for potential commercialization of our product candidates and increased facility-related costs.

Interest expense

Interest expense for 2013 was $10.9 million, compared to $0.5 million for 2012. This increase was primarily attributable to the interest recorded on the loans payable to Hercules Technology Growth Capital, Inc., or Hercules, and the convertible senior notes issued in July 2013.

Other income

Other income for 2013 was $0.6 million, which was primarily related to the amortization of MLSC tax incentives. Other income for 2012 was $1.4 million, which was comprised of $0.6 million of benefit from the remeasurement of fair value of our convertible preferred stock warrants and $0.8 million related to the amortization of MLSC tax incentives.

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Liquidity and Capital Resources

Sources of liquidity

We have financed our operations to date primarily through private placements of our convertible preferred stock, collaborations, public offerings of our securities and a secured debt financing. Through December 31, 2014, we have received $268.2 million from the sale of convertible preferred stock and warrants, $126.7 million of net proceeds from the sale of common stock in our initial public offering and July 2013 follow-on underwritten public offering, $39.6 million of net proceeds from a secured debt financing, $120.6 million of net proceeds from the issuance of the convertible senior notes in our July 2013 underwritten public offering and $342.2 million of upfront license fees, milestone payments, reimbursement of research and development costs and manufacturing services and other payments from our collaborations. We have also entered into an arrangement to use our manufacturing capabilities to manufacture drug product on behalf of Actavis, for which we have received $3.8 million in upfront fees and reimbursements as of December 31, 2014. As of December 31, 2014, we had unrestricted cash and cash equivalents and available-for-sale securities of $124.0 million.

In April 2012, we closed our initial public offering pursuant to a registration statement on Form S-1, as amended. We sold an aggregate of 15,042,459 shares of common stock under the registration statement at a public offering price of $7.00 per share, including 742,459 shares pursuant to the exercise by the underwriters of an over-allotment option. Net proceeds were approximately $98.1 million, after deducting underwriting discounts and commissions and other offering expenses but prior to the payment of dividends on our Series B convertible preferred stock. At the time of our initial public offering, our convertible preferred stock and warrants to purchase convertible preferred stock automatically converted to common stock and warrants to purchase common stock.

On November 8, 2012, we entered into a Loan and Security Agreement, or Loan Agreement, with Hercules. The Loan Agreement provided for an initial term loan advance of $25.0 million, which closed on November 8, 2012, and an additional term loan advance of $15.0 million, which closed on December 14, 2012 and resulted in aggregate net proceeds of $39.6 million.

On July 17, 2013, we sold an aggregate of 5,750,000 shares of our common stock at a price to the public of $5.00 per share and issued $125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020 in concurrent underwritten public offerings. As a result of the concurrent common stock offering and convertible senior notes offering, we received aggregate net proceeds of approximately $147.3 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

As of December 31, 2014, within our unrestricted cash and cash equivalents, $0.3 million was cash and cash equivalents held by our majority owned subsidiary, Silver Creek, which is consolidated for financial reporting purposes. This $0.3 million held by Silver Creek is designated for the operations of Silver Creek.

Cash flows

The following table provides information regarding our cash flows for the years ended December 31, 2014, 2013 and 2012.

	Years ended December 31,		
(in thousands)	**2014**	**2013**	**2012**

Cash used in operating activities	$ (34,808)	$ (95,175)	$ (79,816)
Cash used in investing activities	(6,011)	(27,739)	(75,221)
Cash provided by financing activities	11,421	150,286	142,297
Net (decrease) increase in cash and cash equivalents	$ (29,398)	$ 27,372	$ (12,740)

We invest primarily in U.S. government agencies securities, commercial paper, corporate notes and bonds and certificates of deposit. Our investment objectives are primarily to assure liquidity and preservation of capital

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and secondarily to obtain investment income. All of our investments in debt securities are recorded at fair value and are available-for-sale. Fair value is determined based on quoted market prices and models using observable data inputs. We have not recorded any impairment charges to our fixed income marketable securities as of December 31, 2014.

Operating activities

Cash used in operating activities of $79.8 million during the year ended December 31, 2012 was primarily a result of our $91.8 million net loss, partially offset by non-cash items of $10.0 million and changes in operating assets and liabilities of $2.0 million, which includes receipt of a $5.0 million milestone payment under our license and collaboration agreement with Sanofi. Cash used in operating activities of $95.2 million during the year ended December 31, 2013 was primarily a result of our $130.7 million net loss, partially offset by non-cash items of $18.4 million and changes in operating assets and liabilities of $17.1 million. Cash used in operating activities of $34.8 million during the year ended December 31, 2014 was primarily a result of our $83.6 million net loss, partially offset by non-cash items of $24.9 million and changes in operating assets and liabilities of $23.9 million.

Investing activities

Cash used in investing activities of $75.2 million for the year ended December 31, 2012 was primarily due to the purchase of available-for-sale securities of $115.7 million, which was partially offset by maturities and sales of available-for-sale securities of $43.9 million, as well as $3.2 million related to the purchase of property and equipment and other investing activities. Cash used in investing activities of $27.7 million for the year ended December 31, 2013 was primarily due to purchases of available-for-sale securities net of proceeds from sales and maturities of $17.8 million, as well as $9.9 million of property and equipment purchases. Cash used in investing activities of $6.0 million for the year ended December 31, 2014 was primarily due to $6.0 million of property and equipment purchases.

Financing activities

Cash provided by financing activities of $142.3 million for the year ended December 31, 2012 was primarily a result of $100.0 million of proceeds from our initial public offering, net of offering costs, which closed in April 2012, $41.1 million from us entering into the Loan Agreement with Hercules in November 2012 and Silver Creek entering into the convertible note payable, net of offering costs, and $5.4 million from the issuance of common stock upon the exercise of stock options, partially offset by the payment of $4.2 million of dividends on our Series B convertible preferred stock. Cash provided by financing activities of $150.3 million for the year ended December 31, 2013 was primarily a result of $26.7 million of proceeds from our follow-on underwritten offering of common stock in July 2013, net of offering costs, $120.6 million of proceeds from our underwritten convertible senior notes offering in July 2013, net of offering costs, $2.0 million of proceeds from the exercise of common stock options and $0.9 million of proceeds from the convertible notes offered by Silver Creek, net of offering costs. Cash provided by financing activities of $11.4 million for the year ended December 31, 2014 was primarily a result of $10.4 million of proceeds from the exercise of common stock options and warrants and $1.0 million of proceeds from the convertible notes offered by Silver Creek.

Funding requirements

We have not completed development of any therapeutic products or companion diagnostics, although we have initiated an NDA submission with the FDA for MM-398 as a treatment for metastatic pancreatic cancer in combination with 5-FU and leucovorin in patients who have been previously treated with gemcitabine. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

initiate or continue clinical trials of our six most advanced product candidates;

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

As of December 31, 2014, we had unrestricted cash and cash equivalents and available-for-sale securities of $124.0 million. We expect to be able to fund operations into 2016 through our unrestricted cash and cash equivalents and available-for-sale securities as of December 31, 2014, $66.5 million of net milestones related to MM-398 that we anticipate receiving from Baxter in 2015, after offsetting payments to PharmaEngine, and anticipated cost sharing reimbursements from Baxter. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we utilize collaborations with third parties to participate in their development and commercialization, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future capital requirements will depend on many factors, including:

- the progress and results of the clinical trials of our six most advanced product candidates;
- the success of our collaborations with Baxter and PharmaEngine related to MM-398 and any future collaborations with other parties that we may enter into;
- the timing and amount of anticipated milestone payments and cost sharing reimbursements related to MM-398 that we may receive from Baxter;
- 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 outside the United States and Europe.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external sources of funds, other than our collaboration with Baxter for the development and commercialization of

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MM-398, which is terminable by Baxter for convenience upon 180 days prior written notice, and under our development, license and supply agreement with Actavis, which is terminable by Actavis for convenience in specified circumstances upon 90 days prior written notice. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, if we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Borrowings

4.50% Convertible Senior Notes Due 2020

In July 2013, we issued $125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020. We issued the convertible senior notes under a base indenture between us and Wells Fargo Bank, National Association, as trustee, as supplemented by a supplemental indenture between us and the trustee. As a result of the convertible senior notes offering, we received net proceeds of approximately $120.6 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

The convertible senior notes bear interest at a rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2014. The convertible senior notes are general unsecured senior obligations of ours and rank (i) senior in right of payment to any of our indebtedness that is expressly subordinated in right of payment to the convertible senior notes, (ii) equal in right of payment to any of our unsecured indebtedness that is not so subordinated, (iii) effectively junior in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness, and (iv) structurally junior to all indebtedness and other liabilities (including trade payables) of our subsidiaries.

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

- during any calendar quarter commencing after September 30, 2013 (and only during such calendar quarter), if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

- during the five business day period after any five consecutive trading day period, or the measurement period, in which the trading price (as defined in the convertible senior notes) per $1,000 principal amount of convertible senior notes for each trading day of the measurement period was less than 98% of the product of

the last reported sale price of our common stock and the conversion rate on each such trading day; or

upon the occurrence of specified corporate events set forth in the indenture.

During the fourth quarter of 2014, the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day

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of the calendar quarter ended December 31, 2014 was greater than 130% of the conversion price for the convertible senior notes on each applicable trading day. As a result, holders may convert their convertible senior notes, at their option, at any time from January 1, 2015 through March 31, 2015.

On or after April 15, 2020 until the close of business on the business day immediately preceding the maturity date, holders may convert their convertible senior notes at any time, regardless of the foregoing circumstances. Upon any conversion of convertible senior notes that occurs while our indebtedness to Hercules under the Loan Agreement remains outstanding, the convertible senior notes will be settled in shares of our common stock. Following the repayment and satisfaction in full of our obligations to Hercules under the Loan Agreement, upon any conversion of the convertible senior notes, the convertible senior notes may be settled, at our election, in cash, shares of our common stock or a combination of cash and shares of our common stock.

The initial conversion rate of the convertible senior notes is 160 shares of our common stock per $1,000 principal amount of convertible senior notes, which is equivalent to an initial conversion price of $6.25 per share of common stock. The initial conversion price represents a premium of 25% over the public offering price per share of $5.00 in our concurrent underwritten public offering of common stock. The conversion rate will be subject to adjustment in some events, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the maturity date, we will increase the conversion rate for a holder who elects to convert its convertible senior notes in connection with such a corporate event in certain circumstances.

Upon the occurrence of a fundamental change (as defined in the indenture) involving us, holders of the convertible senior notes may require us to repurchase all or a portion of their convertible senior notes for cash at a price equal to 100% of the principal amount of the convertible senior notes to be purchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The indenture contains customary terms and covenants and events of default with respect to the convertible senior notes. If an event of default (as defined in the indenture) occurs and is continuing, the trustee by written notice to us, or the holders of at least 25% in aggregate principal amount of the convertible senior notes then outstanding by written notice to us and the trustee, may, and the trustee at the request of such holders shall, declare 100% of the principal of and accrued and unpaid interest on the convertible senior notes to be due and payable. In the case of an event of default arising out of certain events of bankruptcy, insolvency or reorganization involving us or a significant subsidiary (as set forth in the indenture), 100% of the principal of and accrued and unpaid interest on the convertible senior notes will automatically become due and payable.

Loan Agreement

In November 2012, we entered into the Loan Agreement with Hercules pursuant to which we received term loans in the aggregate principal amount of $40.0 million in 2012. As permitted under the Loan Agreement, we had previously extended the interest-only payment period with the aggregate principal balance of the term loans to be repaid in monthly installments starting on June 1, 2014 and continuing through November 1, 2016. On June 25, 2014, we entered into an amendment to the Loan Agreement, whereby the period during which we make interest-only payments was extended until October 1, 2014. On November 6, 2014, we entered into a further amendment to the Loan Agreement, whereby the period during which we make interest-only payments was extended until February 1, 2015.

On February 25, 2015, we entered into a further amendment to the Loan Agreement with Hercules pursuant to which we and Hercules agreed to extend the maturity date and the period during which we make interest-only payments on our current term loan in the aggregate principal amount of $40.0 million. As a result of this amendment, we will repay the outstanding aggregate principal balance of the term loan beginning on June 1, 2016 and continuing through

November 1, 2018. If the FDA approves our NDA for MM-398 by May 1, 2016, we may elect to extend the interest-only period by an additional six months so that we would repay the outstanding aggregate principal balance of the term loan beginning on December 1, 2016 and continuing through

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November 1, 2018. In addition, if the FDA approves our NDA for MM-398 by May 1, 2016, we may elect to draw, at any time until August 1, 2016, an additional term loan advance of up to $15.0 million. Principal and interest payments on the additional term loan advance would be made in the same manner as our current term loan in the aggregate principal amount of $40.0 million. For more information, see Part II, Item 9B. Other Information Fourth Amendment to Loan Agreement with Hercules of this Annual Report on Form 10-K.

Our obligations associated with the Loan Agreement are secured by a security interest in all of our personal property now owned or hereafter acquired, excluding intellectual property but including the proceeds from the sale, if any, of intellectual property, and a negative pledge on intellectual property.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of December 31, 2014:

		Payments Due by Period			
(in thousands)	**Total**	**Less than 1 year**	**1 to 3 years**	**3 to 5 years**	**More than 5 years**
Short and long-term loans payable (1)	$ 46,492	$ 16,991	$ 29,501		
4.50% convertible senior notes (1)	158,750	5,625	11,250	11,250	130,625
Operating lease obligations	24,431	5,208	10,824	8,399	
Series B dividends	19	19			
License, collaboration, antibody and technology licensing costs (2)	6,725	5,345	690	690	
Purchase commitment	5,200	5,200			
Total contractual cash obligations	$ 241,617	$ 38,388	$ 52,265	$ 20,339	$ 130,625

(1) Payments are inclusive of interest and principal payments.
(2) License, collaboration, antibody and technology licensing costs include milestone and annual license maintenance fee payments. We have not included annual license maintenance fees or minimum royalty payments after December 31, 2019, as we cannot estimate if they will occur.

Expenditures to contract research organizations represent a significant cost in clinical development. However, our contracts with these research organizations are cancellable at our option upon short notice and do not have cancellation penalties. Therefore, payments to contract research organizations have not been included in the above table.

In January 2011, we received $1.3 million of tax incentives from the MLSC, which allowed us to monetize approximately $1.2 million of state research and development tax credits. In exchange for these incentives, we pledged to hire an incremental 50 employees and to maintain the additional headcount through at least December 31, 2015. Failure to do so could result in our being required to repay some or all of these incentives. This contingent obligation has not been included in the above table as we cannot estimate if or when it will become payable.

In January 2013, the MLSC awarded us an additional $0.5 million of tax incentives under its Life Science Tax Incentive Program, which allows us to monetize approximately $0.4 million of state research and development tax

credits. We received this payment in the fourth quarter of 2013. In exchange for these incentives, we have pledged to hire an incremental 20 employees and to maintain the additional headcount through at least December 31, 2017. Failure to do so could result in us being required to repay some or all of these incentives. This contingent obligation has not been included in the above table as we cannot estimate if or when it will become payable.

In May 2014, the MLSC awarded us an additional $0.6 million of tax incentives under its Life Science Tax Incentive Program, which allows us to monetize approximately $0.6 million of state research and development

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tax credits. In exchange for these incentives, we have pledged to hire an incremental 31 employees and to maintain the additional headcount through at least December 31, 2018. Failure to do so could result in us being required to repay some or all of these incentives. This contingent obligation has not been included in the above table as we cannot estimate if or when it will become payable.

Other than the specific payments noted in the table and as described above, milestone and royalty payments associated with antibody licensing, manufacturing technology licensing costs and other in-licensed collaboration payments have not been included in the above table as management cannot reasonably estimate if or when they will occur. These arrangements include the following:

- Under a collaboration agreement with Dyax related to antibody identification and evaluation, we are required to make aggregate development and regulatory milestone payments of up to $16.2 million for therapeutic products and aggregate regulatory milestone payments of up $1.0 million for diagnostic products directed to selected targets. We also are required to pay mid single digit royalties on net sales of licensed products.

- Under license agreements with The Regents of the University of California, we are required to make aggregate development and regulatory milestone payments of up to $1.3 million associated with MM-111 and MM-302 and pay royalties in the low single digits on net sales of licensed products.

- Under an agreement with Adimab, we are required to make aggregate development and regulatory milestone payments of up to $52.5 million related to therapeutic antibody licensing costs associated with MM-151 and pay mid single digit royalties on net sales of licensed products.

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

During the third quarter of 2013, we issued $125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020. Contractual interest obligations related to the convertible senior notes total $5.6 million due in each year from 2015 through 2020.

As of December 31, 2014, there here have been no other material changes to our contractual obligations and commitments outside the ordinary course of business.

Off-Balance Sheet Arrangements

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

Tax Loss Carryforwards

At December 31, 2014, we had net operating loss carryforwards for federal and state income tax purposes of $432.3 million and $337.7 million, respectively. Included in the federal and state net operating loss carryforwards is approximately $21.1 million of deduction related to the exercise of stock options. This amount represents an excess

tax benefit, which will be realized when it results in reduction of cash taxes in accordance with Accounting Standards Codification 718. This excess tax benefit will be directly credited to additional paid-in capital when it is realized. Our existing federal and state net operating loss carryforwards will expire in years through 2034. We also have available research and development credits for federal and state income tax purposes of approximately $20.8 million and $7.9 million, respectively. The federal and state research and development credits will begin to expire in 2022 and 2024, respectively. As of December 31, 2014, we also have available investment tax credits for state income tax purposes of $0.6 million, which will expire in years through 2017 if not used. In addition we have federal orphan drug credits of $36.1 million that begin to expire in 2031. We have

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evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets, which are comprised principally of net operating loss carryforwards, deferred revenue and capitalized research and development expenses. Under the applicable accounting standards, we have considered our history of losses and concluded that it is more likely than not that we will not recognize the benefits of federal and state deferred tax assets. Accordingly, we have established a full valuation allowance against the deferred tax assets.

Utilization of the net operating loss and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended (the Internal Revenue Code), due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax. We have not currently completed an evaluation of ownership changes through December 31, 2014 to assess whether utilization of our net operating loss or research and development credit carryforwards would be subject to an annual limitation under Section 382 of the Internal Revenue Code. To the extent an ownership change occurs in the future, the net operating loss and credit carryforwards may be subject to limitation.

We have not yet conducted a study of our domestic research and development credit carryforwards and orphan drug credits. This study may result in an increase or decrease to our credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the credits, and if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. As a result, there would be no impact to the statement of comprehensive loss or cash flows if an adjustment were required.

Recent Accounting Pronouncements

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

In May 2014, the FASB issued guidance which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. This guidance will be effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is not permitted. We are currently evaluating the potential impact that the adoption of this guidance and the related transition guidance may have on our consolidated financial statements.

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

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

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

The term loans under the Loan Agreement with Hercules bear interest at variable rates. We have an aggregate principal amount of $40.0 million outstanding under this facility. Interest is payable at an annual rate equal to the greater of 10.55% and 10.55% plus the prime rate of interest minus 5.25%, but may not exceed 12.55%. As a result of the 12.55% maximum annual interest rate, we have limited exposure to changes in interest rates on borrowings under this facility. For each 1% increase in the interest rate on the outstanding debt amount, subject to a maximum 2% increase, we would have an increase in future cash outflows of approximately $0.4 million over the next twelve month period based on the term of the loans as of December 31, 2014.

The convertible senior notes bear interest at a fixed rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2014. As a result, we are not subject to interest rate risk with respect to the convertible senior notes.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-33 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2014. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship

of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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Internal Control Over Financial Reporting

Management s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting for the company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company s principal executive and principal financial officers and effected by the company s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Based on its assessment, management concluded that, as of December 31, 2014, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2014 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Fourth Amendment to Loan Agreement with Hercules

On February 25, 2015, we entered into a fourth amendment to the Loan Agreement, or the loan amendment, with Hercules pursuant to which we and Hercules agreed to extend the maturity date and the period during which we make interest-only payments on our current term loan in the aggregate principal amount of $40.0 million. As a result of the loan amendment, we will repay the outstanding aggregate principal balance of the term loan beginning on June 1, 2016 and continuing through November 1, 2018. If the FDA approves our NDA for MM-398 by May 1, 2016, we may elect to extend the interest-only period by an additional six months so that we would repay the outstanding aggregate principal balance of the term loan beginning on December 1, 2016 and continuing through November 1, 2018.

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If the FDA approves our NDA for MM-398 by May 1, 2016, we may elect to draw, at any time until August 1, 2016, an additional term loan advance of up to $15.0 million. Principal and interest payments on the additional term loan advance would be made in the same manner as our current term loan in the aggregate principal amount of $40.0 million.

The term loan bears interest at an annual rate equal to the greater of 10.55% and 10.55% plus the prime rate of interest minus 5.25%, but may not exceed 12.55%. If the FDA approves our NDA for MM-398 by May 1, 2016, the interest rate on the term loan, including any portion of the additional term loan advance of up to $15.0 million that we may elect to draw, will automatically decrease to an annual rate equal to the greater of 9.45% and 9.45% plus the prime rate of interest minus 5.25%, but may not exceed 11.45%.

On November 1, 2016, we are obligated to pay Hercules the $1.2 million fee that was previously due upon maturity of our current term loan. In addition, if the FDA approves our NDA for MM-398 by May 1, 2016 and we receive the additional term loan advance of up to $15.0 million, we will be obligated to pay Hercules at maturity an additional fee equal to 1.0% of the aggregate principal amount of the additional term loan advance. We paid Hercules a fee of $150,000 upon entering into the loan amendment.

The loan amendment also grants Hercules an option to purchase up to an aggregate of $1.0 million of our equity securities sold to institutional accredited investors in a private financing on or before February 25, 2016 upon the same terms and conditions afforded to such investors.

The foregoing description of the loan amendment to the Loan Agreement does not purport to be complete and is qualified in its entirety by reference to the loan amendment, which is filed as an exhibit to this Annual Report on Form 10-K.

Amendment to Facility Lease

On February 23, 2015, we and DWF IV One Kendall, LLC, or the landlord, entered into a third amendment to our facility lease, or the lease amendment, to further expand our research, manufacturing and office space. The lease amendment provides an additional 31,620 square feet at our current facility in Cambridge, Massachusetts, with a termination date of June 30, 2019, which is co-terminous with our existing lease. The rent for the additional leased space will be an average of $56.50 per rentable square foot during the first year of rent payments, increasing to an annualized average of $59.50 per rentable square foot per year by the end of the lease term. Under the terms of the lease amendment, the landlord will provide us with an aggregate leasehold improvement allowance of up to approximately $790,000.

We retain an option to renew our lease with respect to all of the existing facility, including the additional leased space, for an additional period of either one or five years.

The foregoing description of the lease amendment does not purport to be complete and is qualified in its entirety by reference to the lease amendment, which is filed as an exhibit to this Annual Report on Form 10-K.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included under the captions Executive Officers, Director Nomination Process, Board Policies, Code of Business Conduct and Ethics, Board Meetings and Attendance and Section 16(a) Beneficial Ownership Reporting Compliance in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included under the captions Executive and Director Compensation Processes, Compensation Discussion and Analysis, Summary Compensation Table, Grants of Plan-Based Awards Table, Option Exercises and Stock Vested Table, Employment Agreements, Potential Payments Upon Termination or Change in Control and Compensation Committee Interlocks and Insider Participation in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 will be included under the captions Security Ownership of Certain Beneficial Owners and Management and Securities Authorized for Issuance Under Equity Compensation Plans in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 will be included, as applicable, under the captions Employment Agreements, Potential Payments Upon Termination or Change in Control, Board Determination of Independence and Related Person Transactions in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this Item 14 will be included under the captions Audit Fees and Services and Pre-Approval Policies and Procedures in our definitive proxy statement to be filed with the SEC with respect to our 2015 Annual Meeting of Stockholders and is incorporated herein by reference.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(1) Financial Statements

Our consolidated financial statements are set forth on pages F-1 through F-33 of this Annual Report on Form 10-K and are incorporated herein by reference.

(2) Financial Statement Schedules

Schedules have been omitted since they are either not required or not applicable or the information is otherwise included herein.

(3) Exhibits

The exhibits filed as part of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding such Exhibits, which Exhibit Index is incorporated herein by reference.

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MERRIMACK PHARMACEUTICALS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Merrimack Pharmaceuticals, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of comprehensive loss, statements of convertible preferred stock, non-controlling interest and stockholders deficit, and statements of cash flows present fairly, in all material respects, the financial position of Merrimack Pharmaceuticals, Inc. and its subsidiaries at December 31, 2014 and December 31, 2013, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management s Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express opinions on these financial statements and on the Company s internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

February 27, 2015

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Merrimack Pharmaceuticals, Inc.

Consolidated Balance Sheets

(in thousands, except per share amounts)	December 31, 2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 35,688	$ 65,086
Available-for-sale securities	88,340	90,116
Restricted cash	101	101
Accounts receivable	3,313	5,857
Prepaid expenses and other current assets	4,654	5,484
Total current assets	132,096	166,644
Restricted cash	584	584
Property and equipment, net	14,502	13,364
Other assets	144	175
Intangible assets, net	1,525	1,845
In-process research and development	6,200	6,200
Goodwill	3,605	3,605
Total assets	$ 158,656	$ 192,417
Liabilities, Non-Controlling Interest and Stockholders Deficit		
Current liabilities:		
Accounts payable, accrued expenses and other	$ 37,236	$ 38,814
Deferred revenues	59,275	9,336
Deferred rent	1,285	1,336
Long-term debt, current portion	13,346	8,248
Total current liabilities	111,142	57,734
Deferred revenues, net of current portion	35,682	66,139
Deferred rent, net of current portion	5,401	6,538
Deferred tax incentives, net of current portion	496	507
Long-term debt, net of current portion	106,806	103,427
Accrued interest	1,200	1,200
Total liabilities	$ 260,727	$ 235,545
Commitments and contingencies		
Non-controlling interest	69	337
Stockholders deficit:		
Preferred stock, $0.01 par value: 10,000 shares authorized at December 31, 2014 and 2013, respectively; no shares issued or outstanding at December 31, 2014 or 2013		
	1,067	1,025

Common stock, $0.01 par value: 200,000 shares authorized at December 31, 2014 and 2013, respectively, 106,697 and 102,523 issued and outstanding at December 31, 2014 and 2013, respectively		
Additional paid-in capital	552,037	527,779
Accumulated other comprehensive loss	(74)	(24)
Accumulated deficit	(655,170)	(572,245)
Total stockholders deficit	$ (102,140)	$ (43,465)
Total liabilities, non-controlling interest and stockholders deficit	$ 158,656	$ 192,417

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

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Merrimack Pharmaceuticals, Inc.

Consolidated Statements of Comprehensive Loss

(in thousands, except per share amounts)	Years ended December 31, 2014	2013	2012
Collaboration revenues	$ 102,756	$ 47,786	$ 48,921
Operating expenses:			
Research and development	138,495	147,139	125,858
General and administrative	30,517	21,187	15,805
Total operating expenses	169,012	168,326	141,663
Loss from operations	(66,256)	(120,540)	(92,742)
Other income and expenses			
Interest income	114	166	184
Interest expense	(18,230)	(10,938)	(553)
Other, net	813	627	1,357
Net loss	(83,559)	(130,685)	(91,754)
Less net income (loss) attributable to non-controlling interest	(268)	240	(477)
Net loss attributable to Merrimack Pharmaceuticals, Inc.	(83,291)	(130,925)	(91,277)
Other comprehensive income (loss):			
Unrealized loss on available-for-sale securities	(50)	14	(38)
Other comprehensive income (loss)	(50)	14	(38)
Comprehensive loss	(83,341)	(130,911)	(91,315)
Net loss per share available to common stockholders basic and diluted	($ 0.80)	($ 1.32)	($ 1.28)
Weighted-average common shares used in computing net loss per share available to common stockholders basic and diluted	104,410	98,919	72,831

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

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Merrimack Pharmaceuticals, Inc.

Consolidated Statements of Convertible Preferred Stock, Non-Controlling Interest and Stockholders Deficit

(in thousands)	Series B-G convertible preferred stock Shares	Amount	Non-controlling interest	Common stock Shares	Amount	Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders deficit
Balance at December 31, 2011	64,151	$ 268,225	$ 574	11,834	$ 118	$ 60,231		$ (350,839)	$ (290,490)
Exercise of stock options and common stock warrants				2,693	27	5,400			5,427
Stock-based compensation						6,889			6,889
Conversion of convertible preferred stock into common stock	64,151	268,225		66,256	663	267,562			268,225
Initial public offering, net of issuance costs				15,042	150	97,931			98,081
Series B dividends declared						(4,263)			(4,263)
Conversion of convertible preferred stock warrants to common stock warrants						929			929
Other comprehensive loss							(38)		(38)
Loss attributable to non-controlling interest			(477)					477	477
Net loss								(91,754)	(91,754)
			97	95,825	958	434,679	(38)	(442,116)	(6,517)

Balance at December 31, 2012								
Exercise of stock options and common stock warrants			948	9	2,027			2,036
Stock-based compensation					10,733			10,733
Issuance of common stock in a public offering, net of issuance costs			5,750	58	26,658			26,716
Conversion option of convertible senior notes					51,875			51,875
Conversion of Silver Creek convertible notes payable		796			1,807			1,807
Other comprehensive income						14		14
Loss attributable to non-controlling interest		(556)					556	556
Net loss							(130,685)	(130,685)
Balance at December 31, 2013	$	$ 337	102,523	$ 1,025	$ 527,779	$ (24)	(572,245)	$ (43,465)
Exercise of stock options and common stock warrants			4,174	42	10,383			10,425
Stock-based compensation					13,197			13,197
Conversion of Silver Creek convertible notes payable		366			678			678
Other comprehensive						(50)		(50)

income								
Loss attributable to non-controlling interest		(634)					634	634
Net loss							(83,559)	(83,559)
Balance at December 31, 2014	$	$ 69	106,697	$ 1,067	$ 552,037	$ (74)	(655,170)	$ (102,140)

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

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Merrimack Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows

(in thousands)	Years ended December 31, 2014	2013	2012
Cash flows from operating activities			
Net loss	$ (83,559)	$ (130,685)	$ (91,754)
Adjustments to reconcile net loss to net cash used in operating activities			
Non-cash interest expense	8,511	4,548	78
Depreciation and amortization	3,223	2,589	3,664
Stock-based compensation	13,197	10,733	6,889
Purchased premiums and interest on available-for-sale securities	858	(1,809)	(2,354)
Other non-cash items		579	(587)
Changes in operating assets and liabilities:			
Accounts receivable	2,587	3,410	(1,841)
Prepaid expenses and other current assets	827	4,037	(2,477)
Accounts payable, accrued expenses and other	(646)	13,304	6,985
Deferred revenues	19,482	(4,989)	(5,281)
Deferred rent and tax incentives	712	2,076	7,892
Other assets and liabilities, net		1,032	(1,030)
Net cash used in operating activities	(34,808)	(95,175)	(79,816)
Cash flows from investing activities			
Purchase of available-for-sale securities	(111,832)	(112,923)	(115,665)
Proceeds from sales and maturities of available-for-sale securities	111,858	95,100	43,880
Purchase of property and equipment	(6,035)	(9,857)	(3,189)
Assignment of restricted cash		(57)	(628)
Release of restricted cash			381
Other investing activities, net	(2)	(2)	
Net cash used in investing activities	(6,011)	(27,739)	(75,221)
Cash flows from financing activities			
Proceeds from public offerings, net of offering costs		26,716	100,025
Proceeds from exercise of common stock and warrants	10,384	2,036	5,427
Proceeds from issuance of debt, net of issuance costs	1,044	121,537	41,128
Payments of dividends on Series B convertible preferred stock	(7)	(3)	(4,235)
Other financing activities			(48)
Net cash provided by financing activities	11,421	150,286	142,297
Net increase (decrease) in cash and cash equivalents	(29,398)	27,372	(12,740)
Cash and cash equivalents, beginning of period	65,086	37,714	50,454

Cash and cash equivalents, end of period	$ 35,688	$ 65,086	$ 37,714
Noncash financing and investing activities			
Conversion of convertible preferred stock to common stock			268,225
Conversion of convertible preferred stock warrants to common stock warrants			929
Issuance of derivative liability		35	196
Value of conversion feature of convertible senior notes, classified in Stockholders Deficit		51,876	
Property, plant and equipment in accounts payable and accrued expenses	704		412
Disposals of fully depreciated assets	1,603	210	671
Reclassification of deferred financing costs to stockholders deficit		278	2,748
Dividends on Series B convertible preferred stock declared but not paid			28
Conversion of Silver Creek convertible notes	1,044	2,603	
Supplemental disclosure of cash flows			
Cash paid for interest	$ 9,510	$ 3,915	$ 169

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

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Merrimack Pharmaceuticals, Inc.

Notes to Consolidated Financial Statements

1. Nature of the Business

Merrimack Pharmaceuticals, Inc. (the Company) is a biopharmaceutical company discovering, developing and preparing to commercialize innovative medicines consisting of novel therapeutics paired with companion diagnostics for the treatment of cancer. The Company currently has six targeted therapeutic oncology candidates in clinical development (MM-398, MM-302, MM-121, MM-111, MM-151 and MM-141). The Company s most advanced program is its investigational agent MM-398. The Company has initiated a New Drug Application submission with the U.S. Food and Drug Administration for MM-398 as a treatment for metastatic pancreatic cancer in combination with 5-fluorouracil and leucovorin in patients who have been previously treated with gemcitabine. The Company also has multiple product candidates in preclinical development and a discovery effort advancing additional candidate medicines. The Company also has an agreement to utilize its manufacturing expertise to develop, manufacture and exclusively supply bulk drug to a third party, who will in turn process the drug into a finished product and commercialize it globally. The Company was incorporated in the Commonwealth of Massachusetts in 1993 and reincorporated in the State of Delaware in October 2010.

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

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

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

2. Summary of Significant Accounting Policies

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

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared under U.S. generally accepted accounting principles (GAAP) and include the accounts of the Company and its wholly owned subsidiaries. The Company s wholly owned subsidiaries include Hermes BioSciences, Inc. (Hermes), which was merged with and into the Company during 2011, and Merrimack Pharmaceuticals (Bermuda) Ltd., which was merged

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with and into the Company during the third quarter of 2014. The Company also consolidates its majority owned subsidiary, Silver Creek Pharmaceuticals, Inc. (Silver Creek). All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

GAAP requires the Company s management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. The Company bases estimates and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. The most significant estimates in these consolidated financial statements include, but may not be limited to, revenue recognition, including the estimated percentage of billable expenses in any particular budget period, periods of meaningful use of licensed products, estimated service periods and services to be completed under a collaboration, estimates used in accounting for revenue separability and recognition, useful lives with respect to long-lived assets and intangibles, accounting for stock-based compensation, convertible preferred stock warrants, contingencies, intangible assets, goodwill, in-process research and development, valuation of convertible debt, tax valuation reserves and accrued expenses. The Company s actual results may differ from these estimates under different assumptions or conditions. The Company evaluates its estimates on an ongoing basis. Changes in estimates are reflected in reported results in the period in which they become known by the Company s management.

Segment and Geographic Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment and the Company operates in only one geographic region.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents are short-term, highly liquid investments with original maturities of three months or less at the date of purchase. Investments qualifying as cash equivalents primarily consist of money market funds, commercial paper, corporate notes and bonds and certificates of deposit.

Cash accounts with any type of restriction are classified as restricted cash. If restrictions are expected to be lifted in the next twelve months, the restricted cash account is classified as current. As of both December 31, 2014 and 2013, the Company recorded restricted cash of $685,000, which was primarily related to the Company s facility lease.

Available-for-Sale Securities

The Company classifies marketable securities with a remaining maturity when purchased of greater than three months as available-for-sale. Available-for-sale securities may consist of U.S. government agencies securities, commercial paper, corporate notes and bonds and certificates of deposit, which are maintained by an investment manager. Available-for-sale securities are carried at fair value, with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders deficit until realized. Realized gains and losses are recognized in interest income. Any premium or discount arising at purchase is amortized and/or accreted to interest income. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities during the years ended December 31, 2014, 2013 or 2012.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk consist primarily of cash and cash equivalents, available-for-sale securities and accounts receivable. The Company places its cash deposits in accredited

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financial institutions and, therefore, the Company s management believes these funds are subject to minimal credit risk. The Company invests cash equivalents and available-for-sale securities in money market funds, U.S. government agencies securities and various corporate debt securities. Credit risk in these securities is reduced as a result of the Company s investment policy to limit the amount invested in any one issue or any single issuer and to only invest in high credit quality securities. The Company has no significant off-balance sheet concentrations of credit risk such as foreign currency exchange contracts, option contracts or other hedging arrangements. For each of the years ended December 31, 2014 and 2013, Sanofi represented approximately 90% and 98% of collaboration revenues, respectively. As of December 31, 2014 and 2013, Sanofi represented approximately 50% and 98% of accounts receivable, respectively. Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, Baxter) represented approximately 49% of accounts receivable as of December 31, 2014.

Property and Equipment

Property and equipment, including leasehold improvements, are recorded at cost and depreciated when placed into service using the straight-line method, based on their estimated useful lives as follows:

Asset classification	Estimated useful life (in years)
Lab equipment	3 - 7
IT equipment	3 - 7
Leaseholds improvements	Lesser of useful life or lease term
Furniture and fixtures	3 - 7

Costs for capital assets not yet placed into service have been capitalized as construction-in-progress and will be depreciated in accordance with the above guidelines once placed into service. Costs for repairs and maintenance are expensed as incurred, while major betterments are capitalized. The Company capitalizes interest cost incurred on funds used to construct property and equipment. The capitalized interest is recorded as part of the asset to which it relates and is depreciated over the asset s estimated useful life. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is reflected in earnings.

The Company reviews its long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If impairment is indicated, the asset will be written down to its estimated fair value on a discounted cash flow basis.

Non-Controlling Interest

Non-controlling interest represents the non-controlling stockholders proportionate share of preferred stock and net loss of the Company s majority owned consolidated subsidiary, Silver Creek. The non-controlling stockholders proportionate share of the preferred stock in Silver Creek is reflected as non-controlling interest in the Company s consolidated balance sheets as a component of mezzanine equity.

Revenue Recognition

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

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

The Company entered into a license and collaboration agreement with Baxter in September 2014, which was evaluated under the accounting guidance on revenue recognition for multiple element arrangements. The Company determined that the obligations under this agreement represent a single unit of accounting and that the agreement represents a services agreement. As a result, the Company has estimated the level of effort expected to be completed as a result of providing the identified deliverables and will recognize revenue related to the agreement based on proportional performance as effort is completed over the expected services period.

The Company entered into a collaboration agreement with Watson Laboratories, Inc. (Actavis) in November 2013, which was evaluated under the accounting guidance on revenue recognition for multiple element arrangements. See Note 5, License and Collaboration Agreements, for additional information.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, it determines the period over which the performance obligations would be performed and revenue would be recognized. If the Company cannot reasonably estimate the timing and the level of effort to complete its performance obligations under the arrangement, then revenue under the arrangement is recognized on a straight-line basis over the period the Company expects to complete its performance obligations.

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

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

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses comprise costs incurred in performing research and development activities, including personnel-related costs, stock-based compensation, facilities, research-related overhead, clinical trial costs, contracted services, research-related manufacturing, license fees and other external costs. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the services have been performed or when the goods have been received rather than when the payment is made.

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Stock-Based Compensation

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

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

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions, and other events and circumstances, from non-owner sources and currently consists of net loss and changes in unrealized gains and losses on available-for-sale securities.

Other Income and Expense

The Company records gains and losses on the remeasurement to fair value of convertible preferred stock warrants and other derivative liabilities, the federal and state sponsored tax incentives and other one-time income or expense-related items in other income and expense.

In January 2010, the Massachusetts Life Sciences Center (MLSC), an independent agency of the Commonwealth of Massachusetts, awarded the Company $1.5 million of tax incentives under its Life Sciences Tax Incentive Program. These incentives allowed the Company to monetize approximately $1.4 million of state research and development tax credits. The Company received this payment in 2010. In exchange for these incentives, the Company pledged to hire an incremental 50 employees and retain these employees until at least December 31, 2014. For the years ended December 31, 2014, 2013 and 2012, the Company recognized $0.3 million of benefit in other income in each period.

In January 2011, the MLSC awarded the Company an additional $1.3 million of tax incentives under its Life Sciences Tax Incentive Program, which allowed the Company to monetize approximately $1.2 million of state research and development tax credits. The Company received this payment in the second quarter of 2011. In exchange for these incentives, the Company pledged to hire an incremental 50 employees and retain these employees until at least December 31, 2015. Failure to do so could result in the repayment of some or all of these incentives. The Company deferred and is amortizing the benefit of this incentive on a straight-line basis over the five-year performance period, with a cumulative catch-up in the period the pledge is achieved. For the years ended December 31, 2014, 2013 and 2012, the Company recognized $0.2 million of benefit in other income in each period.

In January 2013, the MLSC awarded the Company an additional $0.5 million of tax incentives under its Life Science Tax Incentive Program, which allows the Company to monetize approximately $0.4 million of state research and development tax credits. The Company received this payment in the fourth quarter of 2013. In exchange for these incentives, the Company pledged to hire an incremental 20 employees and to maintain the additional headcount through at least December 31, 2017. Failure to do so could result in the Company being required to repay some or all of these incentives. The Company deferred and is amortizing the benefit of this incentive on a straight-line basis over the five-year performance period, with a cumulative catch-up in the period the pledge is achieved. For the years ended December 31, 2014 and 2013, the Company recognized $0.1 million of benefit in other income in each period.

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In May 2014, the MLSC awarded the Company an additional $0.6 million of tax incentives under its Life Science Tax Incentive Program, which allows the Company to monetize approximately $0.6 million of state research and development tax credits. In exchange for these incentives, the Company pledged to hire an incremental 31 employees and to maintain the additional headcount through at least December 31, 2018. Failure to do so could result in the Company being required to repay some or all of these incentives. The Company deferred and is amortizing the benefit of this incentive on a straight-line basis over the five-year performance period, commencing with a cumulative catch-up when the pledge was achieved. For the year ended December 31, 2014, the Company recognized $0.1 million of benefit in other income.

Deferred Financing Costs

The Company capitalizes certain legal, accounting and other fees that are directly associated with in-process debt and equity financings as current assets until such financings occur. In the case of an equity financing, after occurrence, these costs are recorded in equity or mezzanine equity, net of proceeds received. In the case of a debt financing, these costs are recorded as assets and amortized over the term of the debt.

In April 2012, the Company closed the initial public offering of its common stock. Upon closing, $2.7 million of deferred financing costs were netted against the equity proceeds within stockholders deficit.

In July 2013, the Company closed a follow-on underwritten public offering of additional shares of common stock and issued convertible senior notes in concurrent public offerings. Upon closing, $0.6 million of aggregate deferred financing costs were netted against the proceeds of these offerings.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which these temporary differences are expected to be recovered or settled. Valuation allowances are provided if based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions and other issues. Reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filing is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Potential interest and penalties associated with such uncertain tax positions are recorded as components of income tax expense. To date, the Company has not taken any uncertain tax positions or recorded any reserves, interest or penalties.

Goodwill and Intangible Assets

Goodwill and indefinite-lived intangible assets, including in-process research and development (IPR&D), are evaluated for impairment on an annual basis or more frequently if an indicator of impairment is present. No impairment of goodwill resulted from the Company s most recent evaluation, which occurred in the third quarter of 2014. The Company s next annual impairment evaluation will be made in the third quarter of 2015 unless indicators arise that would require the Company to evaluate at an earlier date.

When performing an evaluation of goodwill impairment, the Company has the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative two-step impairment test. If the Company elects this option and finds, as a result of the qualitative assessment, that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, further testing is not required. This requires the Company to assess the impact of

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significant events, milestones and changes to expectations and activities that may have occurred since the last impairment evaluation. Significant changes to these estimates, judgments and assumptions could materially change the outcome of the impairment assessment. Alternatively, the Company may elect to not first assess qualitative factors and immediately perform the quantitative two-step impairment test. If such an election occurs, in the first step, the fair value of the Company s reporting unit is compared to the carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of the reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of the reporting unit s goodwill. If the carrying value of the reporting unit s goodwill exceeds the implied fair value, then the Company would record an impairment loss equal to the difference. As described above, the Company operates in one operating segment, which is considered the only reporting unit.

The Company s evaluation of IPR&D impairment included a qualitative assessment to determine whether further impairment testing of indefinite-lived intangible assets was necessary. It was determined that it was not more likely than not that an impairment existed as of the third quarter of 2014 and, therefore, impairment evaluations were not performed.

The Company commences amortization of indefinite-lived intangible assets, such as IPR&D, once the assets have reached technological feasibility or are determined to have an alternative future use and amortizes the assets over their estimated future lives. Amortization of remaining IPR&D has not commenced as of December 31, 2014.

Definite-lived intangible assets, such as core technology, are evaluated for impairment whenever events or circumstances indicate that the carrying value may not be fully recoverable. Definite-lived intangible assets are separate from goodwill and indefinite-lived intangible assets and are deemed to have a definite life. The Company amortizes these assets over their estimated useful lives. The Company has not recorded any impairment charges related to definite-lived intangible assets during the year ended December 31, 2014.

Recent Accounting Pronouncements

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

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

In May 2014, the FASB issued guidance which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to

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

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

3. Marketable Securities

Available-for-sale securities, all of which have maturities of twelve months or less, as of December 31, 2014 consisted of the following:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)		
December 31, 2014:				
Commercial paper	$ 6,493	$	$ (2)	$ 6,491
Corporate debt securities	81,921		(72)	81,849
Total	$ 88,414	$	$ (74)	$ 88,340

The aggregate fair value of securities held by the Company in an unrealized loss position for less than 12 months as of December 31, 2014 was $88.4 million, representing 35 securities. To determine whether an other-than-temporary impairment exists, the Company performs an analysis to assess whether it intends to sell, or whether it would more likely than not be required to sell, the security before the expected recovery of the amortized cost basis. Where the Company intends to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recognized on the statement of comprehensive loss as an other-than-temporary impairment charge. When this is not the case, the Company performs additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where the Company does not expect to receive cash flows, based on using a single best estimate, sufficient to recover the amortized cost basis of a security and amount of the loss recognized in other income (expense).

Available-for-sale securities in an unrealized loss position as of December 31, 2014 consisted of the following:

	Aggregate Fair Value	Unrealized Losses
	(in thousands)	
December 31, 2014:		
Commercial paper	$ 6,493	$ (2)

Corporate debt securities	81,921	(72)
	$ 88,414	$ (74)

The Company does not intend to sell and it is not more likely than not that the Company will be required to sell the above investments before recovery of their amortized cost bases, which may be maturity. The Company determined that there was no material change in the credit risk of the above investments. As a result, the Company determined it did not hold any investments with an other-than-temporary-impairment as of December 31, 2014.

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4. Net Loss Per Common Share

Basic net loss per share is calculated by dividing the net loss available to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss available to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table presents the computation of basic and diluted net loss per share available to common stockholders:

	Years ended December 31,		
(in thousands, except per share amount)	**2014**	**2013**	**2012**
Net Loss Per Share:			
Numerator:			
Net loss attributable to Merrimack Pharmaceuticals, Inc.	$ (83,291)	$ (130,925)	$ (91,277)
Plus: Unaccreted dividends on convertible preferred stock			(2,107)
Net loss available to common stockholders basic and diluted	(83,291)	(130,925)	(93,384)
Denominator:			
Weighted-average common shares basic and diluted	104,410	98,919	72,831
Net loss per share available to common stockholders basic and diluted	$ (0.80)	$ (1.32)	$ (1.28)

As discussed in Note 11, Borrowings, in July 2013, the Company issued $125.0 million aggregate principal amount of 4.50% convertible senior notes due 2020 (the Notes) in an underwritten public offering. Upon any conversion of the Notes while the Company has indebtedness outstanding under the Loan and Security Agreement (the Loan Agreement) with Hercules Technology Growth Capital, Inc. (Hercules), the Notes will be settled in shares of the Company s common stock. Following the repayment and satisfaction in full of the Company s obligations to Hercules under the Loan Agreement, upon any conversion of the Notes, the Notes may be settled, at the Company s election, in cash, shares of the Company s common stock or a combination of cash and shares of the Company s common stock. For purposes of calculating the maximum dilutive impact, it is presumed that the conversion premium will be settled in common stock, inclusive of a contractual make-whole provision resulting from a fundamental change, and the resulting potential common shares included in diluted earnings per share if the effect is more dilutive. The stock options, warrants and conversion premium on the Notes are excluded from the calculation of diluted loss per share because the net loss for the years ended December 31, 2014, 2013 and 2012 causes such securities to be anti-dilutive. The potential dilutive effect of these securities is shown in the chart below:

	Years ended December 31,		
(in thousands)	**2014**	**2013**	**2012**
Common stock warrants	2,381	2,777	2,842
Options to purchase common stock	19,567	20,107	18,066
Conversion of the Notes	25,000	25,000	

5. License and Collaboration Agreements

Baxter

On September 23, 2014, the Company and Baxter entered into a license and collaboration agreement (the Baxter Agreement) for the development and commercialization of MM-398 outside of the United States and Taiwan (the Licensed Territory). As part of the Baxter Agreement, the Company granted Baxter an exclusive,

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royalty-bearing right and license under the Company s patent rights and know-how to develop and commercialize MM-398 in the Licensed Territory. Baxter is responsible for using commercially reasonable efforts to develop, obtain regulatory approvals for and, following regulatory approval, commercializing MM-398 in the Licensed Territory. A joint steering committee comprised of an equal number of representatives from each of Baxter and the Company is responsible for approving changes to the global development plan for MM-398, including all budgets, and overseeing the parties development and commercialization activities with respect to MM-398. Unless otherwise agreed, the Company will be responsible for conducting all clinical trials contemplated by the global development plan for MM-398 and manufacturing all clinical material needed for such trials.

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

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

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

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

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

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

The Company has determined that the collaboration represents a services agreement and as such has estimated the level of effort expected to be completed as a result of providing the identified deliverables. The

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Company will recognize revenue from the non-refundable upfront payment, forecasted non-substantive milestone payments and estimated payments related to discovery, research, development and technology transfer services based on proportional performance as effort is completed over the expected services period, which is estimated to be primarily complete by December 31, 2019. The Company will periodically review and, if necessary, revise the estimated service period related to its collaboration with Baxter.

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

During the year ended December 31, 2014, the Company recognized $10.5 million of revenue associated with these payment amounts. As of December 31, 2014, the Company had $91.2 million of deferred revenue related to the Baxter Agreement, $59.3 million of which is classified as current in the consolidated balance sheets based upon the Company s estimate of revenue that will be recognized as a result of effort expected to be completed within the next twelve months. As of December 31, 2014, the Company had $1.6 million of unbilled accounts receivable outstanding with Baxter.

Sanofi

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

From the effective date of the Sanofi Agreement through December 31, 2014, the Company had received total milestone payments of $25.0 million pursuant to the Sanofi Agreement. Under the Sanofi Agreement, Sanofi was responsible for all MM-121 development and manufacturing costs. Sanofi reimbursed the Company for direct costs incurred in both development and manufacturing and compensated the Company for its internal development efforts based on a full time equivalent rate.

The Company recognized cost reimbursements for MM-121 development services within the period they were incurred and billable. Billable expenses were identified during each specified budget period. For the year ended December 31, 2014, this specified budget period was determined to end December 17, 2014. In the event that total development services expense incurred and expected to be incurred during the same period exceeded the total contractually allowed billable amount for development services during that period, the Company recognized only a percentage of the development services incurred as revenue during that period. This percentage was calculated as total development services expense incurred during the specified budget period divided by the sum of total development services expense incurred, plus estimated development services expense to be incurred during the specified period, multiplied by the total contractually allowed billable amount for development services during the specified period, less development services revenue previously recognized within the specified period.

At the inception of the collaboration, the Company determined that the license, the right to future technology, back-up compounds, participation on steering committees and manufacturing services performance

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obligations comprising the Sanofi Agreement represented a single unit of accounting. As the Company could not reasonably estimate its level of effort over the collaboration, the Company recognized revenue from the upfront payment, milestone payment and manufacturing services payments using the contingency-adjusted performance model over the expected development period, which was initially estimated at 12 years from the effective date of the Sanofi Agreement.

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

During the years ended December 31, 2014, 2013 and 2012, the Company recognized revenue based on the following components of the Sanofi agreement:

	Years ended December 31,		
(in thousands)	**2014**	**2013**	**2012**
Upfront payment	$ 39,306	$ 5,000	$ 5,000
Milestone payment	16,377	2,083	2,975
Development services	18,904	36,283	36,905
Manufacturing services and other	17,709	3,867	3,307
Total	$ 92,296	$ 47,233	$ 48,187

The Company performed development services for which revenue was recognized under the Sanofi agreement in accordance with the specified budget period. During the year and specified budget periods ended December 31, 2013, the Company performed $10.1 million of development services in excess of recognized revenue. Of this amount, approximately $5.8 million was recognized as increased revenue in the year ended December 31, 2014 related to expenses incurred prior to December 31, 2013 upon the Company receiving budget approval for these overruns. During the year ended December 31, 2012, development services approximated recognized revenue.

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

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

	December 31,	
(in thousands)	**2014**	**2013**
Accounts receivable, billed	$ 369	$ 2,357
Accounts receivable, unbilled	1,282	3,417
Deferred revenues	$	$ 73,392

PharmaEngine, Inc.

On May 5, 2011, the Company and PharmaEngine, Inc. (PharmaEngine) entered into an assignment, sublicense and collaboration agreement (the PharmaEngine Agreement) under which the Company reacquired rights in Europe and certain countries in Asia to MM-398. In exchange, the Company agreed to pay PharmaEngine a nonrefundable, noncreditable upfront payment of $10.0 million and up to an additional $80.0 million in aggregate development and regulatory milestones and $130.0 million in aggregate sales

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milestones. During the first quarter of 2012, the Company paid a development milestone of $5.0 million under the PharmaEngine Agreement in connection with dosing the first patient in a Phase 3 clinical trial of MM-398 in pancreatic cancer. PharmaEngine is also entitled to tiered royalties on net sales of MM-398 in Europe and certain countries in Asia. PharmaEngine is not responsible for any future development costs of MM-398 except those required specifically for regulatory approval in Taiwan.

On September 22, 2014, the Company amended the PharmaEngine Agreement to redefine sublicense revenue and reduce the portion of sublicense revenue that the Company is required to pay to PharmaEngine. As a result of this amendment, the Company made a $7.0 million milestone payment to PharmaEngine in September 2014. Additionally, as a result of this amendment, a previously contingent $5.0 million milestone payment is now payable to PharmaEngine upon the earlier of either the U.S. Food and Drug Administration s acceptance of a new drug application for MM-398 or April 30, 2015. Prior to the amendment of the PharmaEngine Agreement, this milestone payment was contingent upon the award of certain specified regulatory designations. These milestone payments were recognized as research and development expense during the year ended December 31, 2014.

During the years ended December 31, 2014, 2013 and 2012, the Company recognized research and development expenses of $12.6 million, $1.5 million and $6.2 million, respectively, related to the PharmaEngine Agreement.

Actavis

In November 2013, the Company and Actavis entered into a development, license and supply agreement pursuant to which the Company will develop, manufacture and exclusively supply the bulk form of doxorubicin HCl liposome injection (the Initial Product) to Actavis. Under the agreement, Actavis is responsible for all costs related to finished product processing and global commercialization. Pursuant to the agreement, additional products may be developed for Actavis in the future. The Company is eligible to receive up to $15.5 million, including $2.0 million upfront, which was received in December 2013, and the remainder in development funding and development, regulatory and commercial milestone payments related to the Initial Product. The Company will also receive a double digit share of net profits on global sales of the Initial Product and any additional products. The Company will manufacture and supply the Initial Product to Actavis in bulk form at an agreed upon unit price. In January 2015, we amended our agreement with Actavis to transfer certain responsibilities from us to Actavis in exchange for reducing the aggregate milestone payments that we are eligible to receive by $0.4 million.

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

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

6. Fair Value of Financial Instruments

The carrying value of financial instruments, including cash and cash equivalents, restricted cash, available-for-sale securities, prepaid expenses, accounts receivable, accounts payable and accrued expenses, and other

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short-term assets and liabilities approximate their respective fair values due to the short-term maturities of these instruments and debts.

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

Recurring Fair Value Measurement

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

As of December 31, 2014

(in thousands)	Level 1	Level 2	Level 3
Assets:			
Cash equivalents money market funds	$ 33,199	$	$
Investments commercial paper		6,491	
Investments corporate debt securities		81,849	

As of December 31, 2013

(in thousands)	Level 1	Level 2	Level 3
Assets:			
Cash equivalents money market funds	$ 47,740		$
Cash equivalents commercial paper		13,998	
Investments commercial paper		$ 49,680	
Investments corporate debt securities		40,436	

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

Non-Recurring Fair Value Measurements

Certain assets, including IPR&D, may be measured at fair value on a non-recurring basis in periods subsequent to initial recognition. During the third quarter of 2013, the Company made a decision to deprioritize and delay efforts to further develop an early-stage preclinical program. As a result of this decision, in connection with the Company s annual impairment test performed in the third quarter of 2013, the fair value estimate for the IPR&D asset related to the early-stage preclinical program incorporated the assumptions of significantly lower estimated cash flows from future revenues and a delay in when those cash flows would occur. The fair value was derived from assumptions that are representative of those a market participant would use in estimating fair value. The impairment analysis resulted in the Company recognizing a $0.8 million impairment charge related to the early-stage preclinical program, which was charged to research and development expense in the third quarter of 2013.

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

	Fair Value as of August 31, 2013 (in thousands)	Valuation Technique		Unobservable Input	Percentage
IPR&D asset	$	Income approach weighted discounted cash flow analysis	Probability	Discount rate	25.7%

Other Fair Value Measurements

The estimated fair value and carrying value of the $125.0 million aggregate principal amount of the Notes was $232.4 million and $125.0 million, respectively, as of December 31, 2014. The Company estimated the fair value of the Notes by using a quoted market rate in an inactive market, which is classified as a Level 2 input.

The estimated fair value and carrying value of the Hercules loans payable was $40.6 million and $40.5 million, respectively, as of December 31, 2014. The Company estimated the fair value of the loans payable by using publically available information related to Hercules portfolio of debt investments based on unobservable inputs, which is classified as a Level 3 input.

7. Consolidated Subsidiaries

Silver Creek Pharmaceuticals, Inc.

On August 20, 2010, the Company acquired a controlling interest in Silver Creek. In December 2012, as described in Note 11, Borrowings, Silver Creek entered into a Note Purchase Agreement pursuant to which it issued convertible notes to various lenders in aggregate principal amounts of $1.6 million in December 2012, $0.3 million in February 2013 and $0.6 million in December 2013. As of December 31, 2013, these outstanding borrowings and related accrued interest of $2.6 million converted to shares of Silver Creek Series A preferred stock at the Series A preferred stock value of $1.00 per share. As a result of changes to the ownership composition of Silver Creek as of December 31, 2013, the non-controlling interest in Silver Creek increased by $0.8 million. During the year ended December 31, 2014, Silver Creek issued convertible notes to various lenders in the aggregate principal amount of $1.0 million. As of December 31, 2014, these outstanding borrowings and an immaterial amount of related accrued interest converted to shares of Silver Creek Series A preferred stock at the Series A preferred stock value of $1.00 per share. As a result of changes to the ownership composition of Silver Creek as of December 31, 2014, the non-controlling interest in Silver Creek increased by approximately $0.4 million. As of December 31, 2014 and 2013, the Company owned approximately 60% and 64% of the voting stock of Silver Creek, respectively, and recorded a non-controlling interest of approximately $0.1 million and $0.3 million, respectively, as a component of mezzanine equity on the Company s consolidated balance sheets based on the terms of the Silver Creek Series A preferred stock.

As of December 31, 2014, the Company consolidated Silver Creek s total assets and total liabilities of $0.3 million and $0.2 million, respectively. As of December 31, 2013, the Company consolidated Silver Creek s total assets and total liabilities of $1.0 million and $0.1 million, respectively.

As of December 31, 2014 and 2013, employees and directors of the Company owned approximately 6% and 7% of the outstanding shares of Silver Creek Series A preferred stock, respectively.

Merrimack Pharmaceuticals (Bermuda) Ltd.

Merrimack Pharmaceuticals (Bermuda) Ltd. was incorporated in Bermuda during 2011 and merged with and into the Company during the third quarter of 2014.

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8. Goodwill and Intangible Assets, Net

As part of the acquisition of Hermes on October 6, 2009 (the Acquisition Date), the Company recognized acquired IPR&D of $7.0 million related to several development programs: an antibody-targeted nanotherapeutic that contains a chemotherapy drug, a nanotherapeutic that contains a chemotherapy drug and other early-stage preclinical programs in the amounts of $2.8 million, $3.4 million and $0.8 million, respectively. The Company also acquired intangible assets of $3.2 million related to core nano-carrier technology. These values were determined at the time of acquisition by estimating the costs to develop the acquired IPR&D into commercially viable products, estimating the net cash flows from such projects and discounting the net cash flows back to their present values. The probability of success factors and discount rates used for each project considered the uncertainty surrounding the successful development of the acquired IPR&D.

As of December 31, 2014 and 2013, none of the IPR&D projects have reached technological feasibility nor do they have any alternative future use. Therefore, the Company has not commenced amortization of those assets. The full value of the antibody-targeted nanotherapeutic that contains a chemotherapy drug and the nanotherapeutic that contains a chemotherapy drug recorded at the Acquisition Date remained unchanged as of December 31, 2014 and 2013. The core technology asset is being amortized on a straight-line basis over a period of ten years, which is management s best estimate of the useful life of this technology. The deprioritization and delay of the other early-stage preclinical programs during the year ended December 31, 2013 resulted in an impairment charge of $0.8 million during the third quarter of 2013.

Changes in the carrying value of goodwill, IPR&D and intangible assets for the years ended December 31, 2014, 2013 and 2012 were as follows:

(in thousands)	Intangible assets	IPR&D	Goodwill
Balance, December 31, 2011	$ 2,485	$ 7,010	$ 3,605
Amortization	(320)		
Balance, December 31, 2012	2,165	7,010	3,605
Amortization	(320)		
Impairment		(810)	
Balance, December 31, 2013	1,845	6,200	3,605
Amortization	(320)		
Balance, December 31, 2014	$ 1,525	$ 6,200	$ 3,605

Definite-lived intangible assets subject to amortization consist of core technology acquired from Hermes. The Company commenced amortization of these assets as of the Acquisition Date on a straight-line basis over a period of ten years, which is the estimated useful life of this technology. Amortization expense is expected to be as follows for the next five-year period:

Years Ended December 31,	(in thousands)
2015	$ 320
2016	320
2017	320
2018	320
2019	$ 245

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9. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31,	
(in thousands)	**2014**	**2013**
Lab equipment	$ 16,214	$ 13,714
IT equipment	3,113	2,701
Leasehold improvements	18,219	10,523
Furniture and fixtures	624	340
Construction in process	472	7,635
	38,642	34,913
Less: Accumulated depreciation	(24,140)	(21,549)
	$ 14,502	$ 13,364

Depreciation expense was $4.2 million, $2.8 million and $3.5 million for the years ended December 31, 2014, 2013 and 2012, respectively. Capitalized interest costs were immaterial for the years ended December 31, 2014, 2013 and 2012.

During the years ended December 31, 2014, 2013 and 2012, the Company disposed of $1.6 million, $0.2 million and $0.7 million, respectively, of fully depreciated assets. There were no recognized impairment charges related to fixed assets in the years ended December 31, 2014, 2013 or 2012.

10. Accounts Payables, Accrued Expenses and Other

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

	December 31,	
(in thousands)	**2014**	**2013**
Accounts payable	$ 2,510	$ 1,889
Accrued goods and services	17,481	7,958
Accrued clinical trial costs	7,637	18,073
Accrued payroll and related benefits	6,166	7,255
Accrued interest	2,956	2,926
Accrued dividends payable	19	25
Deferred tax incentives	467	688
Total accounts payable, accrued expenses and other	$ 37,236	$ 38,814

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11. Borrowings

Future minimum payments under indebtedness agreements outstanding as of December 31, 2014 are as follows:

Years Ending December 31: (in thousands)	4.50% Convertible Senior Notes	Loan Agreement
2015	$ 5,625	$ 16,991
2016	5,625	29,501
2017	5,625	
2018	5,625	
2019 and thereafter	136,250	
	$ 158,750	$ 46,492
Less interest	(33,750)	(5,292)
Less unamortized discount	(44,405)	(1,643)
Less current portion		(13,346)
Loans payable, net of current portion	$ 80,595	$ 26,211

4.50% Convertible Senior Notes

In July 2013, the Company issued $125.0 million aggregate principal amount of Notes in an underwritten public offering. The Company issued the Notes under an indenture, dated as of July 17, 2013 (the Base Indenture) between the Company and Wells Fargo Bank, National Association, as trustee (the Trustee), as supplemented by the supplemental indenture, dated as of July 17, 2013, between the Company and the Trustee (together with the Base Indenture, the Indenture). As a result of the Notes offering, the Company received net proceeds of approximately $120.6 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

The Notes bear interest at a rate of 4.50% per year, payable semiannually in arrears on January 15 and July 15 of each year, beginning on January 15, 2014. The Notes are general unsecured senior obligations of the Company and rank (i) senior in right of payment to any of the Company s indebtedness that is expressly subordinated in right of payment to the Notes, (ii) equal in right of payment to any of the Company s unsecured indebtedness that is not so subordinated, (iii) effectively junior in right of payment to any of the Company s secured indebtedness to the extent of the value of the assets securing such indebtedness, and (iv) structurally junior to all indebtedness and other liabilities (including trade payables) of the Company s subsidiaries.

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

during any calendar quarter commencing after September 30, 2013 (and only during such calendar quarter), if the last reported sale price of the Company s common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the

immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

during the five business day period after any five consecutive trading day period (the measurement period) in which the trading price (as defined in the Notes) per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company s common stock and the conversion rate on each such trading day; or

upon the occurrence of specified corporate events set forth in the Indenture.

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During the fourth quarter of 2014, the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the calendar quarter ended December 31, 2014 was greater than 130% of the conversion price for the Notes on each applicable trading day. As a result, holders may convert their Notes at their option at any time from January 1, 2015 through March 31, 2015.

On or after April 15, 2020 until the close of business on the business day immediately preceding the Maturity Date, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon any conversion of Notes that occurs while the Company s indebtedness to Hercules under the Loan Agreement remains outstanding, the Notes will be settled in shares of the Company s common stock. Following the repayment and satisfaction in full of the Company s obligations to Hercules under the Loan Agreement, upon any conversion of the Notes, the Notes may be settled, at the Company s election, in cash, shares of the Company s common stock or a combination of cash and shares of the Company s common stock.

The initial conversion rate of the Notes is 160 shares of the Company s common stock per $1,000 principal amount of Notes, which is equivalent to an initial conversion price of $6.25 per share of common stock. The initial conversion price represents a premium of 25% over the public offering price per share of $5.00 in the Company s concurrent underwritten public offering of common stock, as described in Note 13, Common Stock. The conversion rate will be subject to adjustment in some events, but will not be adjusted for any accrued and unpaid interest. In addition, following certain corporate events that occur prior to the Maturity Date, the Company will increase the conversion rate for a holder who elects to convert its Notes in connection with such a corporate event in certain circumstances.

Upon the occurrence of a fundamental change (as defined in the Indenture) involving the Company, holders of the Notes may require the Company to repurchase all or a portion of their Notes for cash at a price equal to 100% of the principal amount of the Notes to be purchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Indenture contains customary terms and covenants and events of default with respect to the Notes. If an event of default (as defined in the Indenture) occurs and is continuing, the Trustee by written notice to the Company, or the holders of at least 25% in aggregate principal amount of the Notes then outstanding by written notice to the Company and the Trustee, may, and the Trustee at the request of such holders shall, declare 100% of the principal of and accrued and unpaid interest on the Notes to be due and payable. In the case of an event of default arising out of certain events of bankruptcy, insolvency or reorganization involving the Company or a significant subsidiary (as set forth in the Indenture), 100% of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable.

The Company has separately accounted for the liability and equity components of the Notes by bifurcating gross proceeds between the indebtedness, or liability component, and the embedded conversion option, or equity component. This bifurcation was done by estimating an effective interest rate as of the date of issuance for similar notes which do not contain an embedded conversion option. This effective interest rate was estimated to be 15% and was used to compute the initial fair value of the indebtedness of $71.2 million. The gross proceeds received from the issuance of the Notes less the initial amount allocated to the indebtedness resulted in a $53.8 million allocation to the embedded conversion option. The embedded conversion option was recorded in stockholders deficit and as debt discount, to be subsequently amortized as interest expense over the term of the Notes. Underwriting discounts and commissions and offering expenses totaled $4.4 million and were allocated to the indebtedness and the embedded conversion option based on their relative values. As a result, $2.5 million attributable to the indebtedness was recorded as debt discount, to be subsequently amortized as interest expense over the term of the Notes, and $1.9 million attributable to the embedded conversion option was netted with the embedded conversion option in

stockholders deficit.

For the year ended December 31, 2014, interest expense related to the outstanding principal balance of the Notes was $13.7 million.

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Loan Agreement

In November 2012, the Company entered into the Loan Agreement with Hercules pursuant to which the Company received loans in the aggregate principal amount of $40.0 million. The term loans bear interest at an annual rate equal to the greater of 10.55% or 10.55% plus the prime rate of interest minus 5.25%, but may not exceed 12.55%. Net proceeds from both advances received during the fourth quarter of 2012 were $39.6 million. As permitted under the Loan Agreement, the Company had previously extended the interest-only payment period with the aggregate principal balance of the loans to be repaid in monthly installments starting on June 1, 2014 and continuing through November 1, 2016. On June 25, 2014, the Company entered into an amendment to the Loan Agreement, whereby the Company and Hercules agreed to extend until October 1, 2014 the period during which the Company makes interest-only payments. On November 6, 2014, the Company entered into a further amendment to the Loan Agreement, whereby the Company and Hercules agreed to extend by four additional months the period during which the Company makes interest-only payments. As a result, the Company will repay the aggregate outstanding principal balance of the loan in equal monthly installments of principal and interest (based on a 30 month amortization schedule) beginning on February 1, 2015. The remaining principal balance and interest will be due and payable on November 1, 2016. This amendment was treated as a debt modification for accounting purposes.

At the Company s option, the Company may elect to prepay all or any part of the outstanding term loans without penalty.

In connection with the Loan Agreement, the Company granted Hercules a security interest in all of the Company s personal property now owned or hereafter acquired, excluding intellectual property but including the proceeds from the sale, if any, of intellectual property, and a negative pledge on intellectual property. The Loan Agreement also contains certain representations, warranties and non-financial covenants of the Company. In addition, the Loan Agreement granted Hercules an option to purchase up to an aggregate of $1.0 million of the Company s equity securities sold to institutional accredited investors in a private financing within one year after the closing of the Loan Agreement upon the same terms and conditions afforded to such investors. This option expired on November 8, 2013.

The Loan Agreement defines events of default to include the occurrence of an event that results in a material adverse effect upon the Company s business, operations, properties, assets or condition (financial or otherwise); the Company s ability to perform its obligations when due in accordance with the terms of the Loan Agreement, or upon the ability of Hercules to enforce any of its rights or remedies with respect to such obligations; or the collateral under the Loan Agreement or Hercules liens on such collateral or the priority of such liens. As of December 31, 2014, there have been no events of default under the Loan Agreement.

Upon full repayment or maturity of the loans, the Company is required to pay Hercules a fee of $1.2 million, which has been recorded as a discount to the loans and as a long-term liability on the consolidated balance sheets. Additionally, the Company reimbursed Hercules for costs incurred related to the loans, which has been reflected as a discount to the carrying value of the loans. The Company is amortizing these loan discounts totaling $1.6 million to interest expense over the term of the loans using the effective interest method. For the years ended December 31, 2014 and 2013, interest expense related to the Hercules loans payable were $4.7 million and $4.9 million, respectively.

Convertible Notes Silver Creek

In December 2012, the Company s majority owned subsidiary, Silver Creek, entered into a Note Purchase Agreement pursuant to which it issued convertible notes to various lenders in aggregate principal amounts of $1.6 million in December 2012, $0.9 million during the year ended December 31, 2013 and $1.0 million during the year ended December 31, 2014. The notes issued pursuant to the Note Purchase Agreement bore interest at 6% per annum. Upon

issuance, these convertible notes contained a feature wherein if at any time prior to maturity Silver Creek enters into a qualifying equity financing, defined as a sale or series of related sales of

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equity securities prior to the maturity date and resulting in at least $4.0 million of gross proceeds, the notes would automatically convert into the next qualifying equity financing at a 25% discount. The Company determined that this convertible feature met the definition of a derivative and required separate accounting treatment. The derivative was estimated to be valued at $0.2 million for the year ended December 31, 2012 using a probability-weighted model and was recorded as derivative liability on the consolidated balance sheets. For the years ended December 31, 2014 and 2014, the derivative was remeasured upon conversion of the notes with the gain in remeasurement recognized in other income. The notes matured and converted, along with an immaterial amount of accrued interest into shares of Silver Creek Series A preferred stock on both December 31, 2014 and 2013. Upon conversion, the Company s ownership percentage of Silver Creek outstanding preferred stock decreased from 74% as of December 31, 2012 to 64% as of December 31, 2013 to 60% as of December 31, 2014, and a $0.4 million and $0.8 million increase to non-controlling interest was recognized as of December 31, 2014 and December 31, 2013, respectively.

12. Stock Warrants

The following is a description of the common and convertible preferred stock warrant activity of the Company:

(in thousands, except per share amounts)	Warrants for the Purchase of Common Stock	Weighted Average Exercise Price	Warrants for the Purchase of Convertible Preferred Stock	Weighted Average Exercise Price
Balance December 31, 2011	2,640	$ 2.98	302	$ 3.50
Conversion	302	$ 3.50	(302)	$ 3.50
Exercised	(100)	$ 2.63		
Balance December 31, 2012	2,842	$ 3.05		
Exercised	(65)	$ 2.82		
Balance December 31, 2013	2,777	$ 3.05		
Exercised	(396)	$ 3.38		
Balance December 31, 2014	2,381	$ 3.00		

During the year ended December 31, 2012, warrants to purchase approximately 100,000 shares of common stock were cashless exercised and 71,000 shares of common stock were issued. During the year ended December 31, 2013, warrants to purchase approximately 65,000 shares of common stock were cashless exercised and 35,000 shares of common stock were issued. During the year ended December 31, 2014, warrants to purchase approximately 75,000 shares of common stock were cashless exercised and 38,000 shares of common stock were issued.

13. Common Stock

In July 2013, the Company sold an aggregate of 5.8 million shares of its common stock at a price to the public of $5.00 per share in an underwritten public offering and received net proceeds of approximately $26.7 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

During the first quarter of 2012, the Company amended its certificate of incorporation to increase the number of authorized shares of common stock to 200.0 million shares of $0.01 par value common stock. As of December 31, 2014 and 2013, the Company had 200.0 million shares of $0.01 par value common stock authorized. There were approximately 106.7 million and 102.5 million shares of common stock issued and

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outstanding as of December 31, 2014 and 2013, respectively. The shares reserved for future issuance as of December 31, 2014 and 2013 consisted of the following:

(in thousands)	December 31, 2014	December 31, 2013
Common stock warrants	2,381	2,777
Options to purchase common stock	19,567	20,107
Conversion of the Notes	25,000	25,000

14. Stock-Based Compensation

Prior to 2008, the Company granted equity awards to employees, officers and consultants under the 1999 Stock Option Plan (as amended, the 1999 Plan). In 2008, the Company adopted the 2008 Stock Incentive Plan (as amended, the 2008 Plan) for employees, officers, directors, consultants and advisors and decided that no additional shares of common stock would be issued under the 1999 Plan. The 2011 Stock Incentive Plan (the 2011 Plan) became effective upon closing of the Company s initial public offering in April 2012. Upon effectiveness of the 2011 Plan, no further awards were available to be issued under the 2008 Plan. The 2011 Plan is administered by the Board of Directors of the Company and permits the Company to grant incentive and non-qualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards. The 2011 Plan increased the total number of shares of common stock available to be issued by 3.5 million, for a total of 4.3 million shares. Additional shares also become available for grant by reason of the forfeiture, cancellation, expiration or termination of existing awards. The Company registered 3.4 million and 3.6 million of additional shares of common stock related to the 2011 Plan in February 2013 and March 2014, respectively. As of December 31, 2014, there were 2.0 million shares of common stock available to be issued under the 2011 Plan.

During the years ended December 31, 2014, 2013 and 2012, the Company issued options to purchase 3.9 million, 3.3 million and 3.3 million shares of common stock, respectively. These options generally vest over a three-year period for employees. Options granted to directors during the period from April 2012 through December 2013 vest over a one-year period. All other options granted to directors vest immediately. During the years ended December 31, 2013 and 2012, the Company also issued options to purchase less than 0.1 million shares of common stock to non-employees in each period. The assumptions used to estimate the fair value of options granted to non-employees at the date of grant were materially consistent with those used for employee and director grants.

The Company recognized stock-based compensation expense as follows:

	Years ended December 31,		
(in thousands)	2014	2013	2012
Employee awards:			
Research and development	$ 6,864	$ 5,954	$ 4,234
General and administrative	6,065	4,808	2,510
Stock-based compensation for employee awards	12,929	10,762	6,744
Stock-based compensation for non-employee awards	268	(29)	145
Total stock-based compensation	$ 13,197	$ 10,733	$ 6,889

The stock-based compensation for non-employee awards recognized during the year ended December 31, 2013 was negative due to the change in fair value of the options granted during previous periods.

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The fair value of employee options granted during the years ended December 31, 2014, 2013 and 2012 was estimated at the date of grant using the following assumptions:

	Years ended December 31,		
	2014	2013	2012
Risk-free interest rate	1.6 2.0%	0.1 1.9%	0.7 1.1%
Expected dividend yield	0%	0%	0%
Expected term	5.0 5.9 years	5.3 5.9 years	5.0 5.9 years
Expected volatility	64 72%	67 70%	66 72%

The Company uses the simplified method to calculate the expected term, as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. The computation of expected volatility is based on the historical volatility of comparable companies from a representative peer group selected based on industry and market capitalization. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. Management estimates expected forfeitures based on historical experience and recognizes compensation costs only for those equity awards expected to vest.

The following table summarizes stock option activity:

(in thousands, except per share amounts)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2013	20,107	$ 3.93	6.11	$ 38,348
Granted	3,858	$ 5.56		
Exercised	(3,814)	$ 2.44		
Cancelled	(595)	$ 6.21		
Outstanding at December 31, 2014	19,556	$ 4.47	6.17	$ 133,599
Vested and expected to vest at December 31, 2014	19,296	$ 4.45	6.13	$ 132,172
Exercisable at December 31, 2014	15,009	$ 4.02	5.38	$ 109,347

The aggregate intrinsic value was calculated as the difference between the exercise price of the stock options and the fair value of the underlying common stock. The aggregate intrinsic value of options exercised in 2014, 2013 and 2012 was $19.8 million, $2.7 million and $13.7 million, respectively.

As of December 31, 2014, there was $15.1 million of total unrecognized compensation cost related to nonvested employee stock awards. As of December 31, 2014, the Company expects to recognize those costs over a weighted average period of approximately 1.7 years.

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15. Income Taxes

As a result of losses incurred, the Company did not provide for any income taxes in the years ended December 31, 2014, 2013 and 2012. A reconciliation of the Company s effective tax rate to the statutory federal income tax rate is as follows:

	Year Ended December 31,		
	2014	2013	2012
Federal income tax at statutory federal rate			